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Effects of a comprehensive fruit- and vegetable-promoting school-based intervention in three European countries: the Pro Children Study

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The objective of the present study was to evaluate the effects of the Pro Children intervention on schoolchildren's fruit and vegetable (FV) intake after 1 and 2 years of follow-up. The intervention combined a FV curriculum with efforts to improve FV availability at schools and at home. Effects were examined in a group-randomised trial among 1472 10–11-year-old children from sixty-two schools in Norway, the Netherlands and Spain. FV intake was assessed by means of validated self-administered questionnaires completed before the intervention (September 2003), immediately after the first year of the intervention (May 2004) and 1 year later (May 2005). Data were analysed using multilevel linear regression analyses with age and sex as covariates. Significant intervention effects for FV intake were found at first follow-up in the total sample. The adjusted FV intake reported by the children from intervention schools was 20 % higher than FV intake reported by children from control schools. At 1 year later, a significant impact was only observed in Norway. Positive intervention effects on FV intake occurred both at school and outside school. We conclude that the Pro Children intervention is a promising means to promote European schoolchildren's FV intakes, but mainly fruit intake, in the short term. As shown in Norway, where the intervention was best implemented, the intervention might also result in longer-term effects. Further strategies need to be developed that can improve implementation, have an impact on vegetable intake and can secure sustained effects.

Fruit and vegetable intake: Schoolchildren: School-based interventions

Epidemiological studies have shown an association of adequate intake of fruits and vegetables with decreased risk for CVD, obesity, hypertension and type 2 diabetes mellitus[1,2]. Moreover, fruit and vegetable intake in childhood has now been related to a reduced risk for stroke[2,3]. The WHO and FAO state that promoting the intake of fruit and vegetables has now become a global priority[4,5]. This is especially true in the case for schoolchildren since intake of fruit and vegetables among European children is lower than recommended[6].

During the past decades many school-based fruit and vegetable promotion interventions have been studied, mainly in the USA[7–9]. Only a few dietary interventions aimed at primary schoolchildren have been conducted in Europe (i.e. studies with a follow-up of at least 3 months and including a control group). Recent studies either addressed healthy eating or healthy lifestyle in general or they did not include a fruit and vegetable scheme[10–12], with the exception of one study that aimed at fruit and vegetable promotion with inclusion of fruit and vegetable provision in schools[13,14].

Several elements have been identified as successful key elements of an intervention. Interventions should focus on specific eating behaviours, should be guided by behavioural theory, should devote adequate time and intensity, and preferably include changes in the school environment, personalised feedback and parental involvement; using multimedia or web-based tools may be considered[8,9,15–17]. Within the Pro Children Project a multi-component intervention was developed that incorporated most of these elements[18], guided by the intervention mapping protocol[19,20]. The development of the intervention was based on a review of the existing literature[21], and quantitative[9,22,23] and qualitative[24] studies in nine European countries to gain insight into important and changeable determinants of schoolchildren's fruit and vegetable intake. These studies revealed that an intervention should address a broad range of potential determinants, ranging from more general factors in the physical environment to social and personal determinants. The intervention was designed integrating social cognitive models and ecological models and was designed to be applicable in several European countries[17]. Another new feature was the use of interactive technology such as a web-based tailored feedback tool. The Pro Children intervention has been implemented during 2 years in three different European countries, i.e. Norway, the Netherlands and Spain[17].

The aim of the present paper was to evaluate the effects of the Pro Children intervention on schoolchildren's fruit and vegetable intake after 1 and after 2 years of follow-up[17].

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The results of the present evaluation will contribute to the literature on school-based fruit and vegetable interventions by further testing theory-driven multi-component school-based interventions in different countries in Europe.

Methods

The intervention

The Pro Children intervention consisted of different components: a classroom component, a school component, a family component and one optional component, which differed by intervention site[18].

Classroom curriculum. The classroom curriculum consisted of school education materials consisting of a set of sixteen worksheets with guided activities for the classroom and out of the classroom and a web-based computer-tailored feedback tool[25]. These educational classroom activities addressed the knowledge on recommended intake levels, awareness of the children's own intake, taste and preferences for different kinds of fruits and vegetables and specific skills to prepare or ask for fruit and vegetables.

School component. The school component consisted of the provision of fruit and vegetables, either for free, by means of a subscription programme or as part of the school meals. Providing fruit and vegetables increased the school availability, accessibility and exposure to fruit and vegetables. In Norway a national fruit and vegetable subscription programme exists (www.skolefrukt.no) and therefore children from both the intervention group and the control group were invited to participate in the subscription programme. At participating schools, children that subscribe to the programme receive a piece of fruit or a carrot during lunch or during a fruit break each school day for which the parents pay a fee. In the Netherlands, children from the intervention schools received a piece of fruit, a carrot or cherry tomatoes for free during fruit breaks on two schooldays per week. In Spain, children from the intervention schools received fruit for free during the first 2 months of the intervention period. Intervention schools further explicitly asked the children to bring fruit from home on schooldays; a special fruit break was implemented in all intervention schools on between one to five schooldays per week. In Spain, where children are able to eat school lunches, fruit and vegetables were part of the school lunch at both the intervention schools and control schools during 1–4 d per week.

Family component. The family component encouraged parents to be involved in the project by means of their children's homework assignments, parental newsletters and a parent version of the web-based computer-tailored tool that enabled them to get personalised feedback on their own fruit and vegetable intake levels. The newsletters included a variety of information on fruit and vegetables, announcements about ongoing activities and tips for parents to encourage their children to eat more fruit and vegetables. These activities tried to influence the parents as important role models, advise them on how they can support their children in eating fruit and vegetables, and increase home availability and accessibility.

Optional component. The optional component aimed to encourage community participation in the Pro Children Project. In the Netherlands and Norway the local media was used to raise awareness. In Spain, school health services participated in the project and counselled students during their regular health visits.

Overall the programme used a common standard intervention programme, augmented by some components tailored to country-specific needs. For instance, the content of the school curriculum and educational materials regarding parental involvement were similar in the three countries, tailored somewhat to country-specific issues. The school curriculum, for example, addressed the national recommendations for the intake of fruit and vegetables, while activities directed at parents, such as newsletters, incorporated national information regarding relevant related projects and topics. Also the provision of ready-to-eat fruit and vegetables at school was adapted to the local situation.

The first year of the intervention was most intensive. During the second school year in both the Netherlands and Spain the distribution of fruit and vegetables was continued in exactly the same manner as during the first school year. Also in Norway fruit and vegetables were again provided through the national fruit and vegetable subscription programme; however, during the last months of the second intervention year, i.e. from mid-January until mid-June, all the children in the intervention schools were provided with fruit and vegetables for free. The school curriculum and the activities to involve parents were much less extensive as compared with the first school year, and involved a free fruit and vegetable cookery book, continuation of a computer-tailored fruit and vegetable intervention, and two newsletters.

The specific objective of the present study was to increase fruit and vegetable intake by 20 % in intervention schools compared with control schools. An increase of 20 % was considered to be relevant, detectable and realistic based on effect estimates found in other intervention studies that vary between 0·3 and 0·99 servings per d[9].

Design and participants

The effects of the intervention were examined in a group-randomised trial design among fifth and sixth graders, aged 10–13 years, from sixty-two schools in three European counties, i.e. in the Buskerud County of Norway, in Rotterdam, the Netherlands, and in the Bilbao region, Spain. In each country the schools were randomly assigned to an intervention or control group. Surveys among all participating children were conducted before the intervention (September 2003), immediately after (May 2004) and at the end of the following school year (May 2005).

Sample-size calculations, based on results from the cross-sectional survey[6] taking into account the cluster design[26,27] and the aim to detect a 20 % difference (equalling 40 g total fruit and vegetable intake per d) between the intervention and control schools, revealed a necessary total sample size of 1350 children. Sample-size calculations were also conducted for each country separately.

From the 2106 children that were eligible to participate in the study, 288 children did not participate at baseline due to lack of informed consent or being sick on the day of data collection (response rate 86·3 %). At first follow-up, 152 children, and at second follow-up another 177 children did not participate due to illness on the day of data collection or having changed school during the intervention period.

Children were asked to complete a questionnaire during school hours in the presence of a project worker. Children received another questionnaire to take home for completion by one of their parents.

All data were entered and cleaned in the national centres according to a standardised protocol. All national datasets were pooled and further data processing and quality control was carried out in the Pro Children Data Management Centre at the University of Vienna (for more information on protocols and data management, as well as the Pro Children questionnaires, see www.prochildren.org). Ethical approval for the Pro Children Project was obtained from the medical ethical committees in all three countries. Parents had to provide written consent for their children. Responses were treated anonymously and confidentially.

Measures

Primary outcome measures were the total intake of fruit and vegetables and the intake of fruit and vegetables separately, i.e. the amount (g) of fruit and/or vegetables consumed on the day before the day of data collection (24 h recall). The 24 h recall instrument has previously been described by Haraldsdóttir *et al.*[28]. Briefly, the pre-coded 24 h recall section informed about the previous day's fruit and vegetable consumption by questions about fruit and vegetable intake referring to three different time intervals: (1) before school; (2) school time and lunch; (3) after school, supper, after supper. Amounts were indicated in terms of the number of pieces, slices or portions eaten, and standards were defined for these units[28]. Total fruit and/or vegetable intake was calculated by summarising all answers. Potatoes and dried fruit were not included. Based on the different time frames, fruit and vegetable intake at school and outside school could be estimated for the Norwegian and Spanish children who all have lunch at school. However, in the Netherlands, no school meals are offered at schools and about two-thirds of the children eat at home during the lunch break[29]; consequently estimating fruit and vegetable intake at school and outside school will be biased and will therefore be analysed separately.

Additionally, usual fruit and vegetable intake was assessed by a FFQ and the information from the FFQ was used to verify the findings found with the 24 h recall method. The FFQ was not otherwise used in these analyses. Usual fruit intake was measured with one food-frequency question: 'How often do you usually eat fresh fruit?'. Frequency of vegetable intake was measured by three food-frequency questions: 'How often do you usually eat salad and grated vegetables?', 'How often do you usually eat other raw vegetables?', and 'How often do you usually eat cooked vegetables?'. All four questions had eight response alternatives ranging from 'never' (0) to 'every day, more than twice per day' (7). Mean total frequency of vegetable intake per d was calculated by the sum of frequency of intake of salad or grated vegetables, and raw and cooked vegetables.

Family educational level, a potential confounder, was assessed by a questionnaire completed by the parents, and was categorised based on the number of years of education completed by the parent with the highest educational level: less than 7 years, between 7 and 9 years, between 10 and 12 years and more than 12 years.

Validity and reliability

The questionnaire was tested for validity and reliability before the surveys. Specific information on the development, reliability and validity of the intake part of the questionnaire has been published elsewhere[28]. Briefly, the 24 h recall method was compared with a 24 h weighed food record and gave valid estimates of total fruit and vegetable intake in Denmark and Norway, but indications of overestimation of fruit intake (Portugal) and vegetable intake (Iceland) were found in two of the countries where validation took place.

Recruitment and randomisation

Addresses of eligible primary schools in the three intervention sites were retrieved from governmental organisations. From all eligible schools a random sample (not a random sample in Norway) was taken and these schools were invited for participation. In Norway, the Buskerud County educational authorities provided a list of urban and rural schools, located not too far from Oslo (up to 2 h drive from the University of Oslo) and where there were no known conflicts with other ongoing projects. These schools were then contacted by the project staff. In the Netherlands and Norway a second sample was taken because too many schools from the first sample refused to participate. Schools that agreed to participate were randomly allocated to the intervention and the control arm of the study.

It appeared that the Dutch schools agreeing or refusing participation did not differ regarding number of pupils or number of classes, nor on the average educational level of the neighbourhood in which they were situated. However, in two districts with high proportions of immigrant residents ($> 70\,\%$), schools were more likely to refuse participation. After the schools agreed upon participation, they were randomly assigned to the intervention or control condition.

Respondents and preliminary data handling

As can be seen in the flow diagram (Fig. 1), a total of 2106 students (1115 from the intervention schools and 991 from the control schools) were eligible to participate in the Pro Children Study. A total of 305 students (125 from intervention schools and 180 from control schools) were excluded at baseline, due to sickness on the day of data collection or not having an informed consent (282 subjects; 112 from intervention schools and 170 from control schools), returning unreliable questionnaires (six subjects; five from Spanish intervention schools and one from a Spanish control school) or having too many missing answers at the 24 h recall part of the questionnaire (seventeen subjects; eight from intervention schools and nine from control schools). Of the 1801 children (990 from intervention schools and 811 from control schools) completing the 24 h recall questionnaire at baseline, 122 were sick on the day of the data collection for the first follow-up or had moved to another school and another thirty did not complete the 24 h recall part of the first follow-up questionnaire. This resulted in 152 children considered as drop-outs between the baseline and first follow-up measurement. From the 1649 children with valid 24 h recall data at baseline and first follow-up, 177 did not complete the 24 h recall part of the second follow-up questionnaire, of whom

142 children were sick on the day of data collection or had moved to another school. These cases were all considered to be drop-outs. Complete data on the 24 h recall measures at all three measurements were available for 1472 children. In order to compute scales for assessing determinants of intake, 50 % of the scale items had to be answered. Due to missing values in the determinant part of the questionnaire the number of children that were included in the different

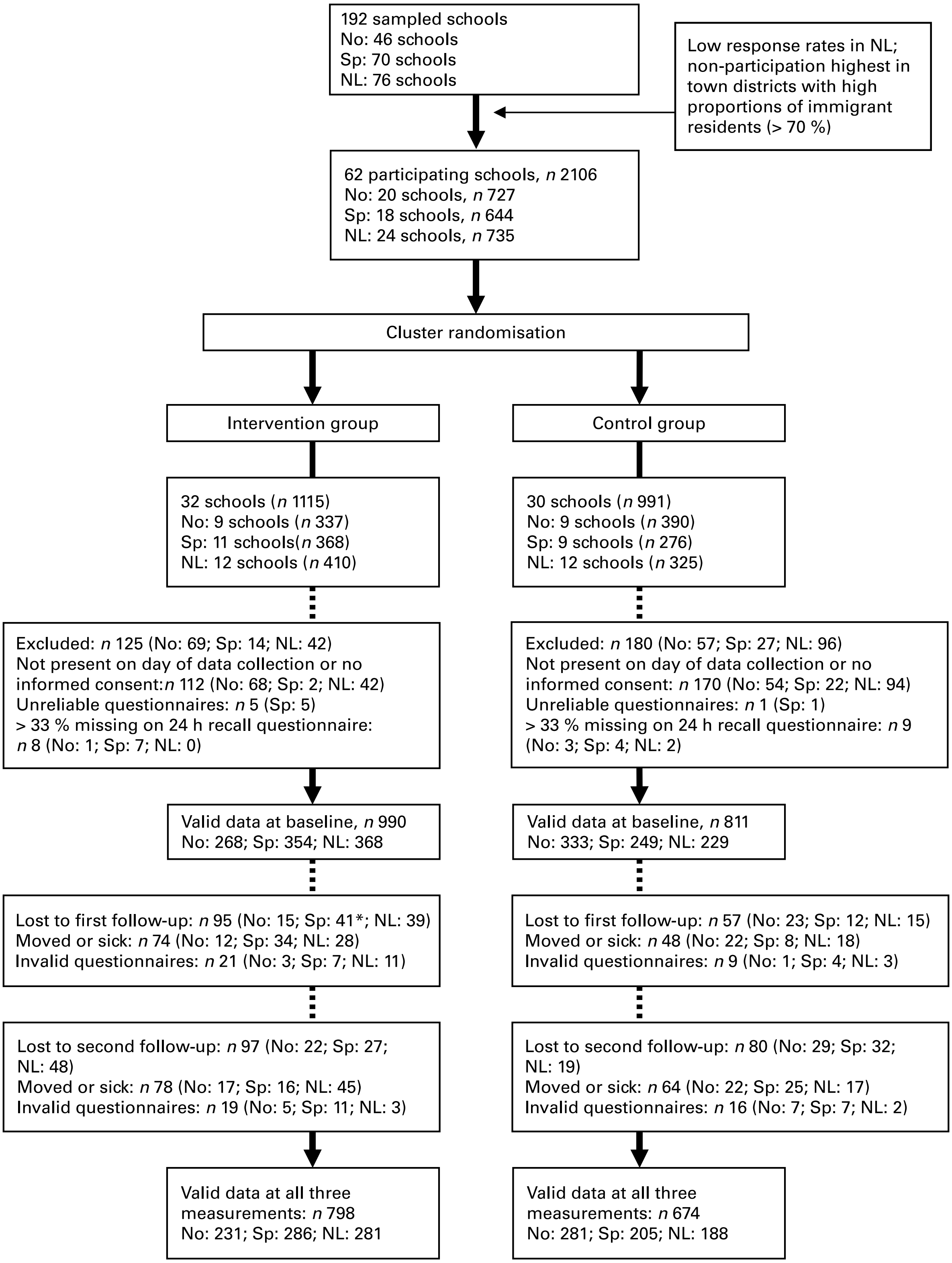

Fig. 1. Flow diagram of the randomisation and inclusion process. No, Norway; Sp, Spain; NL, The Netherlands; *n*, number of pupils. * One Spanish school was lost to first follow-up.

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analyses assessing changes in determinants of fruit intake varied from 1394 to 1419 in the total sample. When assessing changes in determinants of vegetable intake the number of children in the analyses varied from 1095 to1397 for the total sample. Data on the mothers' educational level was available for 1245 children (84·5 %).

Statistical analyses

Descriptive statistics were used to describe key participant characteristics and variable scores for the intervention and control groups at baseline and follow-up. Net differences (Δ) were calculated for changes between baseline and first follow-up and for first follow-up and second follow-up. Net difference was calculated as: (follow-up $\text{intake}_{\text{Intervention}}$ − baseline $\text{intake}_{\text{Intervention}}$) − (follow-up $\text{intake}_{\text{Control}}$ − baseline $\text{intake}_{\text{Control}}$).

Differences at baseline between both groups were explored with Student's *t* test or the χ^2 test. For descriptive purposes only, adjusted mean values for the intake measures at the three different time points were calculated using the ANOVA procedure while adjusting for baseline value, sex and country (except in case of stratified calculations) in SPSS version 14 (1999; SPSS, Inc., Chicago, IL, USA).

Data from the 24 h recall showed large skewed distribution due to the large number of zeros (child did not eat fruit or vegetables on the day before data collection), and log transformation did not result in a normal distribution. Therefore, analyses were conducted on non-transformed data. For all analyses, distributions of the residuals from the regression analyses were checked and considered to be normal.

To assess potential drop-out bias both at the first and second follow-up, multiple logistic regression analysis was conducted with drop-out as the dependent variable and country, sex, age, living circumstances, family educational level, and intake at baseline and treatment condition as independent variables.

As a consequence of the study design, students were nested within schools and we expected a high probability of interdependence between the students of the same schools. To take this into account, multilevel analyses with random intercepts were conducted in MlwiN 2.02 (Institute of Education, London, UK)[30] to assess the effects of the intervention on behaviour, while controlling for sex, age, country and baseline value of the outcome measure. The general idea behind including the baseline value as a covariate in the regression analyses is to correct for the phenomenon of regression to the mean[31]. Before conducting these analyses, potential interaction effects of intervention group with sex, and country were explored with SPSS version 14.0 (SPSS, Inc.) and considered significant when the *P* value for the interaction term was $<0·1$. In case of significant effect modification, analyses were stratified by sex and/or country.

Multilevel modelling with a three-level data structure (time of follow-up measurement (level 1), pupil (level 2) and school (level 3)) and an interaction term between 'time' and group was used to assess time effect of the intervention. In case of significant effect modification by time ($P<0·1$), the direction of the regression coefficient indicates whether the effect was greater (positive direction) or weaker (negative direction) at the second follow-up compared with the first follow-up.

Main analyses were conducted on a complete-cases dataset. Intention-to-treat analyses (last value carried forward method) were conducted to investigate the influence of drop-outs on the effect of the intervention. Additional explorative subgroup analyses were conducted for fruit and vegetable intake at school and outside school and for tertiles of baseline fruit and vegetable intake. All *P* values are two-sided and the 5 % level of significance was used for all other associations.

Results

Drop-out analyses

A total of 152 children dropped out between baseline and first follow-up (thirty-eight (6·3 %) subjects in Norway, fifty-three (8·7 %) subjects in Spain and sixty-one (10·2 %) subjects in the Netherlands). Drop-out analyses showed that children that dropped out more often belonged to the intervention group (OR 2·26; 95 % CI 1·39, 3·68), were more often boys (OR 1·55; 1·01, 2·37), were older (OR 1·04 (95 % CI 1·01, 1·06) for each year) and reported higher vegetable intake at baseline (OR 1·02 (95 % CI 1·00, 1·03) for each 10 g/d). Between the first and second follow-up, another 177 children dropped out (fifty-one (9·0 %) subjects in Norway, fifty-nine (10·7 %) subjects in Spain and sixty-seven (12·5 %) subjects in the Netherlands). The drop-out analyses showed that significantly more Dutch children dropped out (OR 1·71; 95 % CI 1·03, 2·84) and that children that dropped out were older (OR 1·59; 95 % CI 1·03, 2·44).

Descriptives

Table 1 presents the characteristics of the demographic variables for the intervention and control group. The mean age for the intervention group was 10·8 and for the control group 10.7 years; this small difference was statistically significant. Fewer boys than girls participated in the study, but the percentage of boys did not differ between the groups. A significant difference in family educational level was observed between the intervention and control group.

Table 2 shows the observed mean values for the intake of fruit and vegetables for the whole sample and for each country separately. In the whole sample the intervention and control groups did not differ significantly from each other with regard to fruit and vegetable intake, but in Spain the intervention group reported higher total fruit and vegetable intake and higher fruit intake compared with the control group at baseline. The countries also differed with regard to the reported intakes of fruits and vegetables, with Spain reporting significantly lower amounts than Norway and the Netherlands.

Table 2 also presents net differences between the intervention and control groups at first and second follow-up. Largest (unadjusted) net differences were found at first follow-up for total fruit and vegetable intake in the whole sample, the Norwegian and the Dutch sample. At second follow-up, the biggest net differences were found in the Norwegian sample for total fruit and vegetable intake and fruit intake, while in the Spanish and Dutch sample negative net differences are observed.

Effect on intake

In the total sample, significant positive intervention effects were found for all intake measures at the first follow-up

Table 1. Demographic characteristics of the intervention and control group

	Intervention	Control	*P*
Subjects			
Norway (*n*)	231	281	
Spain (*n*)	286	205	
Netherlands (*n*)	281	188	
Age (years)			
Mean	10·8	10·7	<0·001
SD	0·54	0·54	
Boys (*n*)	365	333	
Boys (%)	45·7	49·4	0·088
Families (*n*)	792	669	
Family structure			
Subject lives with both own parents (%)	76·4	77·9	0·271
Subject does not live with both own parents (%)	23·6	22·1	
Subject lives with two adults (%)	85·7	86·8	0·295
Subject lives in single-parent family (%)	14·3	13·2	
Family educational level (*n*)	701	544	
< 7 years (%)	8·3	8·1	0·918
7–9 years (%)	25·2	17·8	0·002
10–12 years (%)	26·0	31·4	0·036
> 12 years (%)	40·5	42·6	0·452

(Table 3). The intervention group reported a 56·9 g/d higher intake of fruit and vegetables than the control group. However, at second follow-up, the intervention effect for total fruit and vegetable intake and vegetable intake differed by country, as indicated by a significant interaction by country (all *P* values $<0·015$). Subsequent analysis by country revealed that at second follow-up the intervention effect was significant only in Norway: the intervention group reported a 91·5 g/d higher intake of fruit and vegetables than the control group.

Furthermore, multilevel modelling with the three-level structure indicated that in Norway the effect of the intervention at second follow-up was significantly higher than at first follow-up for total fruit and vegetable intake and for fruit intake alone ($P<0·05$). In contrast, in Spain and the Netherlands, the effect of the intervention concerning total fruit and vegetable intake decreased at second follow-up. In Spain this was mainly due to weaker effects at second follow-up for fruit intake (Table 3; Fig. 2).

Results of the intervention are also graphically presented in Fig. 2. Fig. 2 shows significant differences in mean intakes between the intervention and control groups at first follow-up ($P<0·05$) and clearly illustrate the findings from the multilevel modelling. Figs. 2 (a) and (c) further show that the children in the Norwegian intervention group increased their intake levels, while the Dutch and Spanish intervention group decreased (Spain) or stabilised (Dutch) their intake levels.

Adjustments for family educational level attenuated the intervention effect at first follow-up, but differences between the intervention and control group were still significant ($P<0·01$ for total fruit and vegetable intake and fruit intake, and $P<0·05$ for vegetable intake; data not shown). At second follow-up, the intervention effect for Norway became even stronger after adjustment for family educational level (regression coefficient 95·2 (95 % CI 52·3, 138·0) g/d for total fruit and vegetable intake). Results found for the usual fruit and vegetable intake according to the FFQ supported the findings from the 24 h recall method. However, the effects for fruit intake based on the FFQ were significant (regression coefficient 0·237 (95 % CI 0·125, 0·349) times/d) for the total sample at second follow-up and no interaction by country was found.

An intention-to-treat analysis showed comparable effect estimates or even stronger and more often statistically significant effect estimates as found using the complete-cases analyses (data not shown). The intention-to-treat analysis resulted in a significant intervention effect in the Netherlands for total fruit and vegetable intake at second follow-up and for fruit intake at second follow-up. These analyses also resulted in a significant intervention effect for vegetable intake at second follow-up in the whole sample.

Additional analyses showed that the achieved changes in fruit and vegetable intake were not due to higher intakes during school hours at first follow-up. Only in the Dutch sample were effects for total fruit and vegetable intake and fruit intake during school hours significant. For intake outside school hours the Norwegian and Spanish sample combined improved their total fruit and vegetable intake and fruit intake, while the Dutch sample only improved their vegetable intake. Results for the second follow-up showed significant effects for intake at school in Norway only and outside school for the combined Norwegian and Spanish sample (no significant interaction by country) (see Table 4).

Moreover, the intervention effects occurred in the whole sample, but the effect size differed (not significant) between subgroups based on baseline intake (i.e. tertiles), ranging between 45 and 65 g/d. Also in Norway, the results at second follow-up did not differ by level of baseline intake (data not shown).

Discussion

The present study indicates that the Pro Children intervention significantly improved fruit and vegetable intakes in schoolchildren at the end of the school year in which the intervention was fully implemented. However, 1 year later during which a less intensive intervention was conducted, a significant impact was only observed among the Norwegian children. At first follow-up the adjusted total fruit and vegetable intake of the intervention group (278 g/d) was 24·6 % higher than the control group (223 g/d), meaning that the initial goal of 20 % increase in fruit and vegetable consumption was reached. At second follow-up, children in the Norwegian intervention schools reported a 38 % higher intake (331 g/d) than children in the control schools (240 g/d). The goal of an increase by 20 % was set because it was considered meaningful, detectable and realistic as based on previous reported results on school-based interventions. Although the goal was reached in the three countries combined at first follow-up, whether these changes are meaningful for public health depends on the reach of the intervention and on the sustainability of the effect. Epidemiological modelling indicates that such small but widely adopted and sustained changes do have meaningful effects in terms of prevention of certain cancers and life expectancy[32,33]. For instance, Veerman *et al.*[33] modelled the effects of a computer-tailored nutrition education, assuming that the intervention reached the entire adult population and

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Table 2. Descriptive statistics for intake variables, by total sample and by country for baseline, first and second follow-up
(Mean values and standard deviations)

	Baseline					First follow-up					Second follow-up				
	Intervention		Control			Intervention		Control			Intervention		Control		
Outcome	Mean	SD	Mean	SD	*P**	Mean	SD	Mean	SD	Δ	Mean	SD	Mean	SD	Δ
All countries															
Total fruit and vegetable intake (g/d)	256	254	264	267	0·598	277	241	224	222	60	260	217	221	200	−14
Total vegetable intake (g/d)	78	117	89	120	0·079	89	123	70	101	30	73	98	63	89	−10
Total fruit intake (g/d)	179	187	175	191	0·708	188	162	154	162	31	187	167	157	157	−4
Norway															
Total fruit and vegetable intake (g/d)	292	298	312	296	0·457	282	239	242	242	60	332	262	241	228	49
Total vegetable intake (g/d)	89	123	98	131	0·437	84	132	74	109	19	74	109	70	102	−6
Total fruit intake (g/d)	203	227	214	208	0·575	199	166	168	175	42	258	205	172	180	55
Spain															
Total fruit and vegetable intake (g/d)	201	199	165	151	0·029	232	182	178	198	17	192	132	171	132	−32
Total vegetable intake (g/d)	54	99	63	65	0·287	67	89	49	91	26	51	51	35	45	−1
Total fruit intake (g/d)	147	145	102	115	$<0·001$	165	132	129	139	−9	141	117	136	116	−31
The Netherlands															
Total fruit and vegetable intake (g/d)	283	256	299	291	0·536	318	284	246	207	88	270	226	243	206	−45
Total vegetable intake (g/d)	93	124	103	143	0·387	116	141	87	95	40	94	119	85	98	−20
Total fruit intake (g/d)	190	184	195	209	0·784	202	184	159	164	48	176	155	158	157	−25

Δ Net difference between intervention and control groups.
* *P* value estimated by Student's *t* test for difference in mean intake between intervention and control groups at baseline.

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Table 3. Results from multilevel regression analyses for the intervention effects at first and second follow-up for the total sample, and for countries separately in case of interaction by country*
(Regression coefficients and 95 % confidence intervals)

	First follow-up			Second follow-up		Interaction by time	
Outcome	Regression coefficient†	95 % CI	Country	Regression coefficient†	95 % CI	Direction‡	*P*
Total fruit and vegetable intake (g/d)	56·9	28·0, 85·9	Norway§	91·5	49·8, 133·2	+	0·044
			Spain§	12·3	−40·8, 65·3	−	0·090
			The Netherlands§	28·7	−12·8, 70·1	−	0·072
Total vegetable intake (g/d)	23·6	7·80, 39·3		9·23	−2·76, 21·2	−	0·120
Total fruit intake (g/d)	34·1	14·3, 54·0	Norway§	87·8	53·7, 121·9	+	0·002
			Spain§	0·01	−46·5, 46·5	−	0·032
			The Netherlands§	17·3	−10·8, 45·4	−	0·175

* Results are adjusted for age, sex, baseline value and country (except for the stratified analyses).
† Regression coefficients reflect the difference between the control (0) and intervention (1) groups.
‡ Positive direction indicates greater effect at second follow-up; negative direction indicates smaller effect at second follow-up.
§ Interaction by country.

the effects were sustained, and showed that this could result in a mortality decrease of 0·4 to 0·7 % and save 72 to 115 life-years per 100 000 individuals aged 25 years or older.

School-based interventions to promote consumption of fruit and vegetables among students in school settings have primarily consisted of multi-component interventions, and those including an environmental intervention component appear to be the most effective[8,34]. Previous interventions promoting fruit and vegetable intake report effects ranging between 0·2 and 0·99 servings per d[7,9,34]. We report an intervention effect of about 57 g total fruit and vegetable intake (first follow-up), which equals 0·57 portions of fruit or about one portion of cooked vegetables[35]; thus the short-term effects of the Pro Children intervention are comparable with the most successful interventions. The one study that reported better results was the High 5 Project conducted in the USA, reporting an adjusted difference between the intervention and control group of 1·58 servings per d at first follow-up and a difference of 0·99 servings per d at second follow-up[36]; however, this finding was not supported by lunch-time

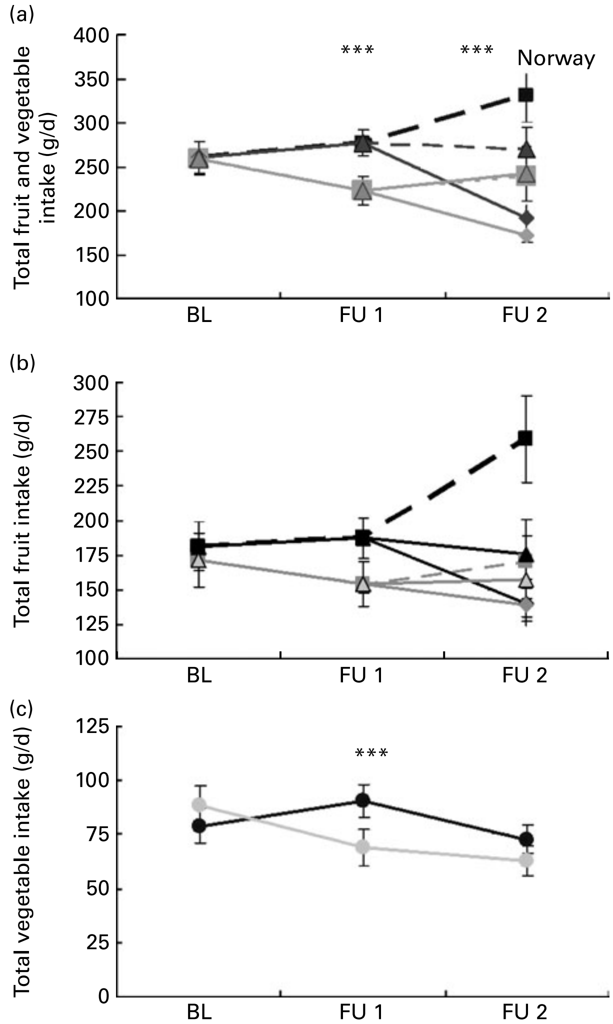

Fig. 2. Changes in total fruit and vegetable intakes (a), total fruit intakes (b) and total vegetable intakes (c) among intervention (■, ◆, ▲) and control (■, ◆, ▲) schools in Norway (■, ■), Spain (◆, ◆) and the Netherlands (▲, ▲). BL, baseline; FU 1, first follow-up; FU 2, second follow-up. *** Intervention effect was significant ($P < 0.05$).

Table 4. Results from multilevel regression analyses for the intervention effects on fruit and vegetable intake at school and outside school*
(Regression coefficients and 95 % confidence intervals)

		First follow-up		Second follow-up	
Intake	Country	Regression coefficient†	95 % CI	Regression coefficient†	95 % CI
During school hours					
Total fruit and vegetables (g/d)	Norway‡	8·7	−8·9, 26·3	57·3	36·0, 78·5
	Spain‡	26·3	−12·7, 65·4	0·3	−42·3, 42·9
	The Netherlands‡	46·6	43·3, 49·9	5·6	−14·1, 25·3
	Norway‡	8·1	−5·3, 21·4	57·8	37·0, 78·6
Fruit (g/d)	Spain‡	12·4	10·1, 14·8	−8·5	−44·7, 27·6
	The Netherlands‡	32·2	12·7, 51·6	7·6	−5·8, 20·9
Vegetables (g/d)	Norway‡	1·1	−2·4, 4·5	1·3	−5·9, 8·5
	Spain‡	5·9	−1·1, 12·8	7·8	−12·7, 28·3
	The Netherlands‡	−0·1	−3·7, 3·4	7·2	−6·6, 21·0
Outside school hours					
Total fruit and vegetables (g/d)	Norway and Spain§	30·5	10·5, 50·5	25·5	6·6, 44·4
	The Netherlands	31·9	−8·0, 71·8	12·0	−17·4, 41·3
Fruit (g/d)	Norway and Spain§	21·0	6·5, 35·4	22·7	6·0, 39·4
	The Netherlands	11·1	−22·6, 44·8	9·7	−12·9, 32·2
Vegetables (g/d)	Norway and Spain§	8·9	−0·3, 18·1	1·6	−6·1, 9·3
	The Netherlands	20·8	5·9, 35·7	2·2	−11·2, 15·5

* All models are adjusted for baseline intake, sex, age (and country).
† Regression coefficients reflect the difference between the control (0) and intervention (1) groups.
‡ Significant interaction by country.
§ Omitting the Netherlands because the majority of Dutch children have lunch at home.

observations at school. This latter fact might indicate biased 24 h recall reports, or that intervention effects mainly occurred outside the school setting. This effect was attained after 2 years of an intensive intervention including a classroom component, a parent component and a food service component. This project also succeeded in involving parents and resulted in an increase in parental fruit and vegetable intakes. Increased parental intake might as well indicate increased fruit and vegetable consumption during family dinner, i.e. outside the school setting. In the Pro Children Study, the first year of the intervention was most intensive with classroom activities and homework assignments, while during the second year of the Pro Children intervention the school curriculum and the activities to involve parents were much less extensive as compared with the first school year. Smaller effects as compared with the High 5 Project and the differences in effect between the three countries might be explained by differences in the distribution of fruit and vegetables or poor implementation of the school curriculum[19,37]. The environmental component of the intervention, i.e. the distribution of fruit and vegetables, differed substantially between the three countries regarding frequency of distribution per week, types of food distributed, time of the day in which the food was handed out to the children and whether parents had to pay to participate. Free fruit and vegetable school-schemes seem to be most promising[13,38], and most effective in increasing fruit intake[39,40]. Although the school curriculum and parental components were more or less similar in the three countries, the level of implementation of these components differed between and within countries[41]. In Norway a home economics teacher is responsible for nutrition education and therefore took care of the Pro Children intervention in cooperation with the main teacher, while the main teacher who is responsible for all education was responsible for the Pro Children intervention in Spain and the Netherlands. Additional analyses, published elsewhere[41], showed that degree of implementation was highest in Norway: on average eleven of the sixteen lessons were implemented in Norway in contrast to a mean of 9·4 lessons in Spain and a mean of only 7·4 lessons in the Netherlands. It was also found that degree of implementation of the school curriculum was associated with effects at first follow-up. It might be that the better implementation of the curriculum in the first year resulted in more improvement in important mediators of fruit and vegetable intake, which subsequently led to continued increase in fruit and vegetable intake in the second year. However, differences in the degree of curriculum implementation during the first intervention year did not explain the differences in achieved intake changes between the countries during the second year, indicating that other factors, such as appreciation of the project by the children and parental involvement may be additional important factors[41].

In contrast to Spain and the Netherlands, children in the Norwegian control schools could also receive fruit and vegetables at school by subscribing to the nationwide fruit and vegetable subscription programme. Subsequently, availability of fruit and vegetables at school might not have been different between the intervention and control schools in Norway, especially in the first year of intervention. This might also explain why intake during school hours was not different between the intervention and control schools in Norway during the first year. Interestingly, significant effects were also observed for outside school intake at first and second follow-up, for total fruit and vegetable intake and fruit intake in the Norwegian and Spanish sample combined and for vegetable intake in the Dutch sample (first follow-up). Therefore, it seems that the effect of the intervention cannot be ascribed to increased school availability alone. Current behaviour-change theory proposes that behaviour change is most likely if individuals have the motivation, abilities and opportunities for change[20]. Providing fruit and vegetables at school increases the opportunity to eat fruit and vegetables, while the school curriculum was meant to increase children's motivation and abilities to eat fruit and vegetables. In Norway the fruit and vegetable scheme was most intensive and for free (from mid-January to mid-June), and the curriculum implementation rate was highest, which may explain the more positive results in this country at second follow-up.

The effects were stronger for fruits than for vegetables. First of all, fruits appeal to children more. Many fruits have a sweet taste for which humans have an innate liking. Second, in Western European countries it is much more common to eat fruit than vegetables in between meals, and the availability of fruit at schools was higher than for vegetables. Furthermore, parents may play a more important role when it comes to increasing their children's vegetable intake compared with fruit intake. Most homework assignments were therefore especially aimed at promoting vegetables. However, the low actual involvement of parents[41] may have made these intervention activities less effective.

In the Dutch sample, the participation rate among schools was relatively low and appeared to be selective with regard to the town districts in which the schools were situated. It might be that this selective participation rate biased the results and limits the generalisability of the findings; however, we can only guess on the direction of the bias.

Furthermore, some indications were found that drop-out depended on study condition. On request of the school staff, one Spanish intervention school dropped out during the intervention period, which fully explains this selective drop-out. Since all children who were present on the day of data collection completed the questionnaires, further drop-out was a consequence of either children leaving school during the intervention period or being sick on the day of data collection. Thus this drop-out was not caused by any conscious choice made by the child itself. We used an intention-to-treat analysis to assess whether higher drop-out of those who were unsuccessful in changing their behaviour explains the positive intervention effects. The intention-to-treat analysis showed comparable effect estimates or even stronger and more often statistically significant effect estimates as found using the complete-cases analyses. These analyses also resulted in a significant intervention effect for vegetable intake at second follow-up in the whole sample. This finding can probably be attributed to sample size, since the effect estimate was only slightly higher (2·4 g/d higher) than what was found in the complete-cases analyses. In the Dutch sample the discrepancy between the complete-cases analyses and the intention-to-treat analyses may be caused by seasonal trends, since the follow-up measurements were in another season to the baseline measurement. In sum, results from the intention-to-treat analyses indicate that there was some selective drop-out, because some extra significant intervention effects were observed. However, this might also be due to a higher number of children included in the analyses.

A valuable product of the Pro Children Study is its questionnaire, which has been validated and is available in several European languages. Although we still strive for improvement in the validity and reliability of the questionnaire, this questionnaire might be useful to standardise measurement of intake across Europe[28]. Furthermore, we did not include a measure of social desirability in the questionnaire, which might be useful to assess potential bias. The cross-European character of the study shows that a similar intervention, but adapted to the local situation (such as participation in a national fruit and vegetable scheme or school lunch), can have some impact across countries with different intake levels[6], determinants of intakes[22], as well as language. A further strength of the present study is the multilevel design with inclusion and randomisation of a substantial sample of schools, using analyses in which we took clustering of children in schools into account.

We used family educational level as an indicator of social class, and adjusting intervention effects for this measure did not lead to different conclusions. We also assessed whether changes mostly occurred at school or in subgroups based on baseline intake levels. Contrary to what might be expected from providing fruit and vegetables at school, the intervention effect on total fruit and vegetable consumption could not solely be explained by higher consumption at school (whole sample first follow-up, Norway second follow-up). Moreover, the intervention effects occurred in the whole sample, and were not dependent on baseline intake levels. This might be caused by the fact that almost all children (89 %) consumed less fruit and vegetables than recommended, giving enough room for improvement, even in the highest intake tertile.

We conclude that the Pro Children intervention is a promising means to promote European schoolchildren's fruit and vegetable intakes, but mainly fruit intake, in the short term. As shown in Norway, where the intervention was best implemented, the intervention might also result in longer-term effects. More research is needed to find the barriers for the poor implementation in the Netherlands and Spain and to find solutions to improve the implementation. A future cost-effectiveness evaluation must give insight in the cost-effectiveness of the Pro Children Study.

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