THE EVALUATION OF UNPLUGGED IN NIGERIA: FOLLOW-UP DATA AND EFFECTIVENESS OF THE PROGRAM

1. Study design and sample size

1.1. Study design

The evaluation of effectiveness of Unplugged in Nigeria was performed designing and conducting a cluster randomized controlled trial with two arms (cluster RCT). The schools were randomly assigned to the Unplugged experimental group or to the Usual Curriculum control group.

The evaluation involved the federal schools of the entire territory of Nigeria. The Federal Ministry of Education provided a list of 65 federal schools based in the 7 Zones of the country, available to participate in the study. Five schools participated in the pilot study, so they were excluded from the experimental study.

The randomization took place by zone. The overall number of schools to involve in the evaluation study was decided based on sample size calculations. Number of schools to be randomized to intervention and control arms in each zone was decided based on the size of the zones' population: 4 schools in North Central zone, 2 in Abuja Federal Territory, 4 in North East zone, 6 in North West zone, 4 in South East zone, 4 in South South zone, 8 in South West zone.

Three classes per school were invited and participated in the evaluation study, both in intervention and in control arm.

1.2. Sample size calculation

Assuming alpha 0.05 (two-sided), power 0.80, prevalence in the control arm 14.6% and in the intervention arm 10.2%, 45 pupils per class, ICC 0.025, the estimated sample size needed was set to 1943 pupils per group (overall 3886), corresponding to 14 schools in the intervention and 14 schools in the control arm. To overcome possible drop-outs from the study. The number of schools allocated to intervention and control arm was enlarged to 16 schools in the intervention and 16 in the control arm.

2. Baseline and Follow-up survey: participation

2.1. Baseline

Thirty-two schools, 96 classes and **4078** pupils participated in the baseline survey (Table 1). In the control arm the number of participants were in line with what expected from rough calculations, but in the intervention arm a certain level of drop out occurred, and the number of participants was only 82.9% of what expected. The difference in participation at baseline caused a bias for differential participation rate in the two arms, and reduced the level of reliability of the intervention arm sample, because of likely selection and sample size (the size of intervention sample at baseline was lower than that needed for the study to reach statistical significant differences according to sample size calculations).

2.2. Follow-up

Thirty-two schools, 99 classes (96 + 3 participating for error in the survey) and **4053** pupils participated in the follow-up survey (Table 1). Again, in the control arm the number of participants was in line with what expected from preliminary rough calculations and with baseline participants, whilst in the intervention arm a drop out of 8% occurred.

2.3. Matched sample

Baseline (n=4078) and follow-up questionnaires (n=3900, excluded 153 pupils participating for error in the survey) were matched through complex matching procedures. Automatic procedures and manual matching were applied, leaving 679 follow-up questionnaires not matching with baseline. The matched sample finally included **3342** pupils with both baseline and follow-up questionnaires. The matching rate was again higher among control (85.6%) than among intervention pupils (77.3%). This difference further increased the differential bias among intervention (sample size only 64% of expected) and control arm (90% of expected) already affecting the two surveys, and further reduced the reliability of the intervention sample.

Moreover, the matched sample was 14% lower than that needed for the study to reach statistical significant differences according to sample size calculations (n=3886).

Drop-out vs expected was particularly high in intervention schools of North West (59.8%), South West (41.5%), FCT (38.5%), North Central (33.7%) and North East (33.7%) zones.

Table 1. Schools and classes enrolled in the study and participants in the baseline survey

Study arm	Zone	Expected	Baseline participants			Follow-up participants			Matched sample baseline-follow-up		Matched vs expected
		pupils	schools	classes	pupils	schools	classes	pupils	pupils	%	%
Control	North Central	270	2	6	288	2	6	272	228	79.2	84.4
	FCT	135	1	3	146	1	3	152	133	91.1	98.5
	North East	270	2	6	298	2	6	274	215	72.1	79.6
	North West	405	3	9	386	3	9	388	297	76.9	73.3
	South East	270	2	6	322	2	9*	478*	304	94.4	112.6
	South South	270	2	6	290	2	6	278	250	86.2	92.6
	South West	405	3	9	402	3	9	408	384	95.5	94.8
	Lagos	135	1	3	156	1	3	164	147	94.2	108.9
	Total	**2160**	**16**	**48**	**2288**	**16**	**51***	**2414***	**1958**	**85.6**	**90.7**
Intervention	North Central	270	2	6	245	2	6	240	179	73.1	66.3
	FCT	135	1	3	129	1	3	113	83	64.3	61.5
	North East	270	2	6	211	2	6	193	179	84.8	66.3
	North West	405	3	9	279	3	9	241	163	58.4	40.2
	South East	270	2	6	242	2	6	233	216	89.3	80.0
	South South	270	2	6	239	2	6	225	210	87.9	77.8
	South West	405	3	9	314	3	9	270	237	75.5	58.5
	Lagos	135	1	3	131	1	3	124	117	89.3	86.7
	Total	**2160**	**16**	**48**	**1790**	**16**	**48**	**1639**	**1384**	**77.3**	**64.1**
Total		**4320**	**32**	**96**	**4078**	**32**	**99***	**4053**	**3342**	**82.0**	**77.4**

* In South East zone, control arm, 3 classes (153 pupils) participated in the follow-up by error; they were included in the follow-up sample but excluded from denominator of the matching rate calculations

3. Report on follow-up survey

3.1. Differences in general characteristics and substance use behaviours

Four-thousand-fifthly-three pupils filled the follow-up questionnaire: 2414 pupils in the control arm and 1639 in the intervention arm (Table 2).
A higher proportion of females was observed in the intervention arm (37.9% vs 30.7%, p<0.0001); and intervention pupils were younger (p=0.029) and had higher grades at school (p=0.002). No differences were observed as regards family composition (the majority of pupils lived with both parents), number of family cars, and family computers.

The differences in the proportion of pupils using substances in the intervention and control arms could be due to the exposure of intervention pupils to the program: however, differences observed in the unadjusted analyses must be better studied adjusting for confounding factors and cluster effect at the level of zone and school. The latter analyses will be performed and results described in the next chapters. In this chapter, we will describe the unadjusted differences in order to have a first look at possible effects of the program.

Class climate was significantly higher in the intervention pupils: this could be an effect of the program (p=0.004) (Table 2).
Apparently, the proportion of pupils who smoked at least one cigarette in last 30 days was not different in the intervention and control arms; however, the proportion of **regular and daily users of cigarettes** was in favour of intervention pupils (difference slightly significant, p=0.07 and p=0.08 respectively).
The proportion of pupils who drunk alcohol at least once in the last 30 days was not different in the intervention and control arms, but again the proportion of **regular and daily users of alcohol** was in favour of intervention pupils (difference slightly significant, p=0.08 and p=0.06 respectively).
No difference was detected between the arms in the proportion of pupils declaring at least one episode of drunkenness in the last 30 days; the same was observed for regular drunkenness episodes, at least one episode of marijuana use, regular marijuana use, at least one episode of other drugs use, and regular drugs use.

Table 2. Differences in general characteristics and behaviours of follow-up participants by arm

Characteristics	Control N=2414		Intervention N=1639		P value
	n	%	n	%	
Gender					
Male	1663	69,4	998	62,1	0.000
Female	735	30,7	610	37,9	
Age					
10-13 years	307	12,7	201	12,6	
14 years	794	32,9	588	36,7	0,029
15 years	680	28,2	449	28,0	
16-20 years	633	26,2	363	22,7	
Family composition					
Both parents	1408	58,7	911	56,2	0,231
Only one parent	174	7,3	134	8.3	
Other	816	34,0	575	35,5	
Family car					
None	437	18,2	268	16,5	0,357
One	969	40,3	658	40,5	
Two or more	998	41,5	698	43,0	
Family computers					
None	396	16,6	241	14,8	
One	585	24,5	409	25,2	0,232
Two	478	20,0	358	22,0	
More than two	934	39,0	616	37,9	
Grades at school					
High	1065	44,9	807	50,5	0,002
Medium	1175	49,6	701	43,9	
Low	131	5,5	89	5,6	
Class climate					
Good	1824	76,6	1292	80,8	0,004
Medium	437	18,4	230	14,4	
Bad	121	5,1	78	4,9	
Cigarettes use					
Last 30 days ALO	98	4,1	63	3,9	0,721
Last 30 days Regular	51	2,2	22	1,4	0,069
Last 30 days Daily	37	1,6	15	0,9	0,085
Alcohol drinking					
Last 30 days ALO	526	22,3	346	21,5	0,530
Last 30 days Regular	283	12,0	165	10,3	0,084
Last 30 days Daily	97	4,1	48	3,0	0,061
Drunkenness episodes					
Last 30 days ALO	112	4,7	85	5,3	0,429
Last 30 days Regular	61	2,6	45	2,8	0,671
Marijuana use					
Lifetime	231	9,6	186	11,5	0,060
Last 30 days ALO	86	3,6	58	3,6	0,976
Last 30 days Regular	64	2,7	36	2,2	0,364
Other drugs use					
Last 30 days ALO	128	5,4	98	6,1	0,355
Last 30 days Regular	72	3,0	51	3,2	0,813

3.2. Differences in knowledge, intentions, beliefs, risk perceptions, attitudes and skills

No differences in knowledge about cigarettes and alcohol were detected in the intervention and control arms (Table 3). Therefore, apparently, the program did not improve knowledge about cigarettes and alcohol.

A significantly higher proportion of pupils of the intervention arm answered correctly to the questions investigating knowledge on marijuana: the program improved knowledge on marijuana effects on physical dependence and sexual hormones.

No differences in the indicators (positive and negative) of beliefs about cigarettes and marijuana were detected in the intervention and control arms (Table 4). Therefore, apparently, the program did not affect beliefs about cigarettes and marijuana.

Negative beliefs about alcohol were significantly in favour of intervention pupils (p=0.004). This could be the mediator of the effect of the program on alcohol use.

No differences in the indicators of risk perception of smoking one or more packs of cigarettes per day, drink alcohol every day and smoke marijuana regularly were detected in the intervention and control arms.

No differences in the indicators of positive and negative attitudes towards illegal drugs were detected: apparently, the program did not have an effect on attitudes towards drugs.

No differences in the indicators (positive and negative) of self-esteem and decision making were observed in the intervention and control arms (Table 5). The program did not affect self-esteem and decision making skills.

Also the intentions to refuse cigarettes, alcohol or marijuana when offered from a friend appear not to be related to the exposure to the program.

A difference in the proportion of pupils with high communication skills was observed in favour of control arm.

Table 3. Differences in knowledge and intentions of follow-up participants by arm

Characteristics	Control N=2414		Intervention N=1639		P value
	n	%	n	%	
Tobacco					
Nicotine is the substance in cigarettes that causes lung cancer					0,988
Yes/Don't know	2262	94,6	1523	94,7	
No (correct)	128	5,4	86	5,3	
One needs to smoke several cigarettes/day to become addicted					0,842
Yes/Don't know	1429	59,8	953	59,5	
No (correct)	959	40,2	648	40,5	
Correct answers					0,803
0 correct answers	1375	57,2	919	56,8	
1 correct answers	967	40,3	662	40,9	
2 correct answers	60	2,5	36	2,2	
Alcohol					
Women have lower tolerance to alcohol than men					0,179
Yes (correct)	1386	58,1	966	60,2	
No/ Don't know	1000	41,9	638	39,8	
It takes about 30 minutes to eliminate from the body the alcohol contained in a can of strong beer					0,217
Yes/Don't know	2078	87,3	1373	85,9	
No (correct)	303	12,7	225	14,1	
Correct answers on alcohol drinking					0,189
0 correct answers	886	40,0	553	34,4	
1 correct answers	1333	55,6	923	57,3	
2 correct answers	178	7,4	134	8,3	
Marijuana					
Smoking marijuana does not cause physical dependence					0,047
Yes/Don't know	1408	58,9	892	55,7	
No (correct)	983	41,1	709	44,3	
High consumption of marijuana decreases sexual hormones					0,000
Yes (correct)	910	38,2	726	45,4	
No/ Don't know	1475	61,8	874	54,6	
Correct answers on marijuana					0,000
0 correct answers	975	40,7	542	33,7	
1 correct answers	943	39,4	701	43,5	
2 correct answers	475	19,9	367	22,8	

Table 4. Differences in beliefs, risk perceptions and attitudes toward drugs of follow-up participants by arm

Characteristics	Control N=2414		Intervention N=1639		P value
	n	%	n	%	
Tobacco					
Positive beliefs					0,603
Low	1263	54,0	836	53,3	
Middle	634	27,1	415	26,5	
High	443	18,9	317	20,2	
Negative beliefs					0,109
High	1123	47,8	803	51,0	
Middle	477	20,3	313	19,9	
Low	749	31,9	458	29,1	
Risk perception: smoke one or more packs of cigarettes per day					0,111
No risk/Slight risk/ Don't know	536	22,6	396	24,7	
Great risk	1841	77,5	1205	75,3	
Alcohol					
Positive beliefs					0,320
Low	1246	53,2	813	51,9	
Middle	644	27,5	422	26,9	
High	451	19,3	333	21,2	
Negative beliefs					0,004
High	1075	45,7	804	51,1	
Middle	525	22,3	317	20,2	
Low	751	31,9	452	28,7	
Risk perception: drink alcohol every day					0,474
No risk/Slight risk/ Don't know	585	24,6	411	25,6	
Great risk	1794	75,4	1195	74,4	
Marijuana and other drugs					
Positive beliefs					0,802
Low	1332	56,7	873	55,6	
Middle	537	22,9	369	23,5	
High	480	20,4	327	20,8	
Negative beliefs					0,403
High	1371	58,1	919	58,2	
Middle	300	12,7	239	15,1	
Low	690	29,2	421	26,7	
Risk perception: smoke marijuana regularly					0,089
No risk/Slight risk/ Don't know	426	17,9	321	20,0	
Great risk	1958	82,1	1283	80,0	
Attitudes towards illegal drugs					
Positive indicator					0,772
Low	1749	73,5	1177	73,9	
Middle/High	630	26,5	415	26,1	
Negative indicator					0,224
High	1509	63,4	983	61,5	
Middle/Low	872	36,6	616	38,5	

Table 5. Differences in self-esteem and skills indicators of follow-up participants by arm

Characteristics	Control N=2414		Intervention N=1639		P value
	n	%	n	%	
Self-esteem					
Positive indicator					
High	1868	81,8	1238	79,9	0,138
Middle/Low	416	18,2	312	20,1	
Negative indicator					
Low	484	21,4	350	22,9	0,290
Middle/High	1775	78,6	1180	77,1	
Decision making skills					
Positive indicator					
High	1258	53,2	866	54,4	0,639
Middle	910	38,5	606	38,1	
Low	195	8,3	120	7,5	
Negative indicator					
Low	721	30,5	487	30,6	0,646
Middle	1144	48,3	749	47,1	
High	503	21,2	356	22,4	
Intention to refuse an offer of a friend of					
Cigarettes					
High	2132	90,1	1436	89,9	0,799
Low	234	9,9	162	10,1	
Alcohol					
High	1863	78,9	1249	78,4	0,705
Low	498	21,1	344	21,6	
Marijuana					
High	2082	87,9	1385	86,6	0,238
Low	287	12,1	214	13,4	
Any substance					
High	1988	84,0	1344	84,1	0,957
Low	379	16,0	255	16,0	
Communication skills					
High	1746	73,9	1130	71,0	
Middle	565	23,9	394	24,8	0,001
Low	53	2,2	68	4,3	

3.3. Differences in parents' behaviours

Parental behaviours can't be affected by the exposure to the program, so the aims of this analysis are just descriptive. Some of the factors here described could actually moderate the effect of the program, and they will be in case taken into account in specific analyses.

The proportion of pupils having at least one parent smoking cigarettes and drinking alcohol was not different between arms (Table 6).

Parental permissiveness towards cigarettes was higher among intervention pupils, whilst parental permissiveness towards alcohol was not different in the intervention and control pupils.

All the others factors related to parental behaviours were not significantly different among the arms.

Table 6. Differences in parents' behaviors of follow-up participants by arm

Characteristics	Control N=2414		Intervention N=1639		P value
	N	%	N	%	
At least one parent smoking cigarettes	81	3,4	56	3,5	0,876
If you wanted to smoke, your father and mother…					
Wouldn't allow at all	2138	89,8	1381	86,6	0,021
Wouldn't allow smoking at home	102	4,3	88	5,5	
Would allow	36	1,5	27	1,7	
Don't know	106	4,5	98	6,2	
If you will smoke cigarettes, you will..					0,099
Get into trouble with parents	1542	66,0	1084	68,5	
At least one parent drinking alcohol	587	24,6	374	23,4	0,373
If you wanted to drink alcohol, your father and mother…					
Wouldn't allow at all	1957	82,3	1303	81,8	0,276
Wouldn't allow drinking at home	143	6,0	115	7,2	
Would allow	107	4,5	58	3,6	
Don't know	172	7,2	117	7,3	
If you will drink alcohol, you will..					0,125
Get into trouble with parents	1527	64,9	1069	67,2	
If you will take marijuana or other drugs, you will..					0,528
Get into trouble with parents	1607	67,8	1096	68,8	
Parental monitoring score					
High	2117	89,4	1405	88,3	0,259
Low	251	10,6	187	11,8	
I can easily get support from my father and/or mother	1898	80,1	1235	77,7	0,077
It is very important for me not to disappoint my parents	2131	89,7	1405	88,3	0,155

3.4. Differences in the perception of peers' and friends' behaviours

In European countries, the use of substances is related to the perception of peers' behaviours, which is generally very high, and prevention programs aims to reduce this misperception. However, in the Nigerian study, the perception of friends and peers using substances was very low and the proportion of those declaring they do not know how many friends and peers smoke, drink, get drunk and use marijuana were quite high, making it very difficult the evaluation of the effectiveness of the program on these outcomes.

However, **a higher propotion of pupils thinking that none or less that half of their peers and friends smoke, drink, get drunk and use marijuana was observed in the intervention than in the control arm** (Table 7). This could be an effect of the program.

Table 7. Differences in perceptions of peers' and friends' behaviors of follow-up participants by arm

Characteristics	Control N=2414		Intervention N=1639		P value
	n	%	N	%	
People of same age smoking cigarettes					
none/less than half/about half	1560	65,2	1131	70,0	0,001
more than half/all of them	269	11,2	179	11,1	
don't know	565	23,6	306	18,9	
People of same age drinking alcohol					
none/less than half/about half	1480	62,0	1053	65,6	0,002
more than half/all of them	356	14,9	256	15,9	
Don't know	551	23,1	297	18,5	
People of same age getting drunk					
none/less than half/about half	1552	65,2	1108	69,3	0,001
more than half/all of them	228	9,6	169	10,6	
don't know	601	25,2	323	20,2	
People of same age using marijuana or other drugs					
none/less than half/about half	1526	64,0	1066	66,5	0,046
more than half/all of them	141	5,9	110	6,9	
don't know	718	30,1	428	26,7	
Friends smoking cigarettes					
none/less than half/about half	1859	78,0	1245	77,9	0,007
more than half/all of them	88	3,7	90	5,6	
don't know	435	18,3	263	16,5	
Friends drinking alcohol					
none/less than half/about half	1805	75,7	1228	76,6	0,000
more than half/all of them	123	5,2	123	7,7	
don't know	455	19,1	252	15,7	
Friends getting drunk					
none/less than half/about half	1820	76,3	1252	78,0	0,000
more than half/all of them	87	3,6	90	5,6	
don't know	480	20,1	264	16,4	
Friends using marijuana or other drugs					
none/less than half/about half	1871	78,2	1268	79,0	0,000
more than half/all of them	71	3,0	83	5,2	
don't know	451	18,9	254	15,8	

3.5. Logistic regression analyses: crude effectiveness results (overall sample)

Univariate logistic regression confirmed the lack of difference in the proportion of last 30 days cigarette users in the intervention and control arms, and the **slightly significant difference in the proportion of regular and daily cigarettes users cigarettes** (Table 8).
Similar results were observed for alcohol: the proportion of last 30 days alcohol users was not different in the intervention and control arms, but again a **slightly significant difference was detected in the proportion of regular and daily drinkers**.
No difference between the arms was detected in drunkenness episodes, marijuana use and other drugs use.

Statistically significant differences were observed **in favour of intervention pupils for knowledge on marijuana, negative beliefs on tobacco and alcohol, and reduction of the perception of use of tobacco and alcohol among peers, and for the improvement of class climate** (Table 9). A statistically significant difference **in favour of control pupils was observed on communication skills**.

These differences need to be studied in stratified and adjusted analysis, controlling for confounding factors and for cluster effect.

Table 8. Unadjusted Odds Ratios of behavioural outcomes, attitudes, beliefs, risk perceptions, self-esteem and skills at follow-up, intervention vs control pupils - (expected to be reduced)

Oucomes	Crude OR	95% CI	P value
Behaviours			
Cigarettes use			
Last 30 days ALO	0,94	0,62-1,30	0,721
Last 30 days Regular	0,63	0,38-1,04	0,072
Last 30 days Daily	0,59	0,32-1,08	0,089
Alcohol drinking			
Last 30 days ALO	0,95	0,82-1,11	0,530
Last 30 days Regular	0,84	0,68-1,02	0,085
Last 30 days Daily	0,72	0,50-1,02	0,062
Drunkenness episodes			
Last 30 days ALO	1,12	0,84-1,50	0,429
Last 30 days Regular	1,09	0,74-1,61	0,671
Marijuana use			
Last 30 days ALO	0,99	0,71-1,40	0,976
Last 30 days Regular	0,83	0,55-1 25	0,364
Other drugs use			
Last 30 days ALO	1,14	0,87-1,49	0,355
Last 30 days Regular	1,05	0,73-1,50	0,813
Beliefs			
Positive beliefs on tobacco			
High vs Middle/Low	1,09	0,92-1,27	0,320
Positive beliefs on alcohol			
High vs Middle/Low	1,13	0,96-1,32	0,131
Positive beliefs on marijuana and drugs			
High vs Middle/Low	1,03	0,88-1,20	0,758
Attitudes			
Positive attitudes towards illegal drugs			
Middle/High vs Low	0,98	0,85-1,13	0,772
Self-esteem			
Negative self-esteem			
Middle/High vs Low	0,92	0,79-1,07	0,290
Decision making skills			
Negative decision making			
Middle/High vs Low	0,99	0,87-1,14	0,924

Table 9. Unadjusted Odds Ratios of knowledge, risk perception, self-esteem, skills, class climate and perception of peers' prevalence at follow-up, intervention vs control pupils - (expected to be increased)

Oucomes	Crude OR	95% CI	P value
Knowledge			
Nicotine is the substance in cigarettes that causes lung cancer			
No (correct) vs Yes/Don't know	1,00	0,75-1,32	0,988
One needs to smoke several cigarettes/day to become addicted			
No (correct) vs Yes/Don't know	1,01	0,89- 1,15	0,842
Correct answers on tobacco			
1/2 correct answers vs 0	1,02	0,90-1,15	0,797
Women have lower tolerance to alcohol than men			
Yes (correct) vs No/Don't know	1,09	0,96-1,24	0,179
It takes about 30 minutes to eliminate from the body the alcohol contained in a can of strong beer			
No (correct) vs Yes/Don't know	1,12	0,93-1,35	0,217
Correct answers on alcohol			
1/2 correct answers vs 0	1,12	0,98-1,28	0,091
Smoking marijuana does not cause physical dependence			
No (correct) vs Yes/Don't know	1,14	1,00-1,29	0,047
High consumption of marijuana decreases sexual hormones			
Yes (correct) vs No/Don't know	1,35	1,18-1,53	0,000
Correct answers on marijuana and drugs			
1/2 correct answers vs 0	1,35	1,19-1,55	0,000
Risk perception			
Smoke one or more packs of cigarettes per day			
Great risk vs No risk/Slight/Don't know	0,89	0,76-1,03	0,111
Drink alcohol every day			
Great risk vs No risk/Slight/Don't know	0,95	0,82-1,10	0,474
Smoke marijuana regularly			
Great risk vs No risk/Slight/Don't know	0,87	0,74-1,02	0,089
Beliefs			
Negative beliefs on tobacco			
High vs Middle/Low	1,14	1,00-1,29	0,049
Negative beliefs on alcohol			
High vs Middle/Low	1,24	1,09-1,41	0,001
Negative beliefs on marijuana and drugs			
High vs Middle/Low	1,00	0,88-1,44	0,934
Attitudes			
Negative attitudes towards illegal drugs			
High vs Middle/Low	0.92	0.81-1.05	0.224
Self-esteem			
Positive self-esteem			
High vs Middle/Low	0,88	0,75-1,04	0,138
Decision making skills			
Positive decision making			
High vs Middle/Low	1,05	0,92-1,19	0,473
Intention to refuse an offer of a friend of			
Cigarettes			
High vs Low	0,97	0,79-1,20	0,799
Alcohol			
High vs Low	0,97	0,83-1,13	0,705
Marijuana			
High vs Low	0,89	0,74-1,08	0,238
Any substance			
High vs Low	1,00	0,84-1,19	0,957
Communication skills			
High vs Middle/Low	0,87	0,75-1,00	0,046
Class climate			
Good vs Medium/Bad	1,28	1,10-1,50	0,002
Peers' prevalence			
none/less than half/about half smoke cigarettes	1.25	1.09-1.43	0.001
none/less than half/about half drink alcohol	1.17	1.02-1.33	0.022
none/less than half/about half get drunk	1.20	1.05-1.38	0.008
none/less than half/about half use marijuana or other drugs	1.11	0.98-1.27	0.108

*vs more than half/all of them/don't know

3.6. Logistic regression analyses: males and females samples

The stratification of follow-up results by gender did not add much information on the effect of the program (Table 10, Table 11). Indeed, no differences among genders emerged in behaviours and knowledge outcomes, and sparse differences were observed in other outcomes. Probably because of low sample size, most of results lost statistical significance.

Table 10. Unadjusted Odds Ratios of behavioural and knowledge outcomes at follow-up, intervention vs control pupils, by gender

Oucomes	Males (N=2661)			Females (N=1345)		
	Crude OR	95% CI	P value	Crude OR	95% CI	P value
Behaviors						
Cigarettes use						
Last 30 days ALO	1,06	0,75-1,50	0,752	0,71	0,26-1,97	0,514
Last 30 days Regular	0,72	0,42-1,22	0,224	0,59	0,11-3,26	0,549
Last 30 days Daily	0,68	0,36-1,28	0,232	0,60	0,54-6,58	0,672
Alcohol drinking						
Last 30 days ALO	1,03	0,86-1,24	0,734	0,86	0,64-1,16	0,324
Last 30 days Regular	0,86	0,68-1,09	0,211	0,96	0,62-1,49	0,865
Last 30 days Daily	0,79	0,53-1,68	0,237	0,59	0,25-1,38	0,225
Drunkenness episodes						
Last 30 days ALO	1,27	0,92-1,76	0,145	0,89	0,45-1,75	0,729
Last 30 days Regular	1,36	0,90-2,07	0,146	0,52	0,16-1,71	0,284
Marijuana use						
Last 30 days ALO	1,12	0,77-1,62	0,549	0,65	0,24-1,75	0,391
Last 30 days Regular	0,96	0,62-1,51	0,874	0,39	0,11-1,46	0,163
Other drugs use						
Last 30 days ALO	1,22	0,90-1,67	0,204	0,99	0,55-1,79	0,977
Last 30 days Regular	1,01	0,68-1,52	0,953	1,70	0,64-4,49	0,286
Knowledge on tobacco						
Nicotine is the substance in cigarettes that causes lung cancer						
No (correct) vs Yes/Don't know	1,04	0,76-1,45	0,791	0,87	0,47-1,61	0,650
One needs to smoke several cigarettes/day to become addicted						
No (correct) vs Yes/Don't know	1,03	0,88-1,21	0,710	1,04	0,84-1,30	0,703
Correct answers						
1/2 correct answers vs 0	1,04	0,89-1,22	0,622	1,04	0,83-1,29	0,740
Knowledge on alcohol						
Women have lower tolerance to alcohol than men						
Yes (correct) vs No/Don't know	1,16	0,99-1,36	0,066	0,93	0,74-1,16	0,517
It takes about 30 minutes to eliminate from the body the alcohol contained in a can of strong beer						
No (correct) vs Yes/Don't know	1,15	0,92-1,44	0,210	1,21	0,86-1,71	0,268
Correct answers						
1/2 correct answers vs 0	1,21	1,03-1,43	0,021	0,95	0,75-1,19	0,633
Knowledge on marijuana						
Smoking marijuana does not cause physical dependence						
No (correct) vs Yes/Don't know	1,11	0,94-1,30	0,213	1,22	0,98-1,51	0,080
High consumption of marijuana decreases sexual hormones						
Yes (correct) vs No/Don't know	1,26	1,08-1,48	0,004	1,57	1,26-1,97	0,000
Correct answers						
1/2 correct answers vs 0	1,30	1,10-1,53	0,002	1,47	1,17-1,84	0,001

Table 11. Unadjusted Odds Ratios of attitudes, beliefs, risk perceptions, self-esteem, skills, class climate and perception of peers' prevalence at follow-up, intervention vs control pupils, by gender

Oucomes	Males (N=2661)			Females (N=1345)		
	Crude OR	95% CI	P value	Crude OR	95% CI	P value
Tobacco						
Positive beliefs						
High vs Middle/Low	1,10	0,90-1,33	0,350	1,06	0,79-1,43	0,685
Negative beliefs						
High vs Middle/Low	1,07	0,91-1,26	0,403	1,23	0,99-1,54	0,061
Alcohol						
Positive beliefs						
High vs Middle/Low	1,18	0,98-1,44	0,088	1,04	0,79-1,39	0,762
Negative beliefs						
High vs Middle/Low	1,12	0,96-1,32	0,141	1,47	1,18-1,83	0,001
Marijuana and other drugs						
Positive beliefs						
High vs Middle/Low	1,12	0,92-1,35	0,273	0,86	0,65-1,13	0,281
Negative beliefs						
High vs Middle/Low	0,89	0,75-1,04	0,140	1,28	1,02-1,60	0,034
Attitudes towards drugs						
Positive attitudes						
Middle/High vs Low	1.07	0.89-1.27	0.483	0.79	0.61-1.02	0.072
Negative attitudes						
High vs Middle/Low	0.82	0.70-0.97	0.018	1.08	0.85-1.36	0.540
Self-esteem						
Positive indicator						
High vs Middle/Low	0,89	0,73-1,09	0,253	0,89	0,66-1,18	0,416
Negative indicator						
Middle/High vs Low	0,86	0,71-1,05	0,131	1,01	0,78-1,32	0,921
Decision making skills						
Positive indicator						
High vs Middle/Low	1,12	0,95-1,31	0,177	0,93	0,75-1,16	0,511
Negative indicator						
Middle/High vs Low	0,98	0,83-1,17	0,839	1,02	0,81-1,29	0,861
Intention to refuse an offer of a friend of						
Cigarettes						
High vs Low	0,90	0,71-1,15	0,401	0,93	0,57-1,53	0,781
Alcohol						
High vs Low	0,98	0,81-1,18	0,804	0,78	0,58-1,05	0,106
Cannabis						
High vs Low	0,83	0,67-1,03	0,094	0,94	0,61-1,44	0,772
Any substance						
High vs Low	1,00	0,82-1,23	0,971	0,80	0,55-1,16	0,238
Communication skills						
High vs Middle/Low	0,91	0,76-1,09	0,311	0,83	0,65-1,06	0,133
Class climate						
Good vs Medium/Bad	1.30	1.07-1.58	0.008	1.19	0.91-1.56	0.212
Peers' prevalence						
none/less than half/about half smoke cigarettes	1.19	1.00-1.42	0.046	1.42	1.14-1.79	0.002
none/less than half/about half drink alcohol	1.21	1.03-1.44	0.023	1.15	0.92-1.44	0.221
none/less than half/about half get drunk	1.19	1.00-1.42	0.045	1.31	1.04-1.64	0.020
none/less than half/about half use marijuana or other drugs	1.21	1.02-1.43	0.029	1.05	0.84-1.31	0.651

*vs more than half/all of them/don't know

3.7. Logistic regression analyses: younger and older pupils

The stratification of follow-up results by age did add some information on the effect (Table 12, Table 13) and confirmed **a difference in the effect by age** that needs to be taken into account in the adjusted analysis.

No differences between age groups emerged in cigarette, drunkenness, marijuana and other drugs behaviours.
The proportion of **last 30 days alcohol drinkers was significantly lower (-26%) among 10-14 years old pupils of intervention vs control arm**, as well as the proportion of **regular alcohol drinkers (more than 6 times in the last month) that was 37% lower among 10-14 years old pupils of intervention vs control arm**. On the contrary, no difference between the arms was detected in the older age group, **suggesting a stronger effect of the program on alcohol outcomes in the younger age group.**

No difference between age groups was detected on tobacco and alcohol knowledge outcomes, and also **the statistically significant difference in favour of intervention pupils on marijuana knowledge was quite independent from age**.

No difference by age was detected for other outcomes (beliefs, attitudes, skills) but **the difference in the perception of good class climate and on the perception of peers' prevalence in favour of intervention pupils was statistically significant only among the younger group**. Again, these results suggest **a stronger effect of the program in the younger age group**.

From these data, there is some indication that the program was effective among younger pupils reducing alcohol use, reducing the perception of peers' prevalence of cigarettes and alcohol use, improving knowledge on marijuana and improving class climate.

Table 12. Unadjusted Odds Ratios of behavioural and knowledge outcomes at follow-up, intervention vs control pupils, by age

Oucomes	10-14 years old (N=1890)			15-20 years old (N=2125)		
	Crude OR	95% CI	P value	Crude OR	95% CI	P value
Behaviors						
Cigarettes use						
Last 30 days ALO	0,76	0,36-1,60	0,473	1,08	0,75-1,55	0,671
Last 30 days Regular	0,46	0,12-1,71	0,248	0,72	0,42-1,25	0,249
Last 30 days Daily	0,70	0,13-3,80	0,675	0,63	0,33-1,20	0,162
Alcohol drinking						
Last 30 days ALO	0,74	0,58-0,94	0,012	1,20	0,98-1,47	0,078
Last 30 days Regular	0,63	0,45-0,88	0,006	1,06	0,81-1,37	0,678
Last 30 days Daily	0,80	0,42-1,52	0,490	0,73	0,48-1,12	0,147
Drunkenness episodes						
Last 30 days ALO	1,36	0,78-2,37	0,284	1,12	0,79-1,57	0,533
Last 30 days Regular	1,17	0,50-2,72	0,719	1,13	0,72-1,76	0,605
Marijuana use						
Last 30 days ALO	0,77	0,35-1,68	0,510	1,16	0,79-1,70	0,445
Last 30 days Regular	0,97	0,37-2,57	0,957	0,87	0,55-1,38	0,554
Other drugs use						
Last 30 days ALO	1,18	0,73-1,90	0,509	1,21	0,87-1,69	0,256
Last 30 days Regular	1,39	0,66-2,94	0,383	1,04	0,68-1,59	0,855
Knowledge on tobacco						
Nicotine is the substance in cigarettes that causes lung cancer						
No (correct) vs Yes/Don't know	1,02	0,64-1,63	0,925	1,06	0,74-1,50	0,766
One needs to smoke several cigarettes/day to become addicted						
No (correct) vs Yes/Don't know	1,07	0,89-1,29	0,471	0,96	0,80-1,15	0,674
Correct answers						
1/2 correct answers vs 0	1,07	0,89-1,29	0,470	0,98	0,82-1,71	0,824
Knowledge on alcohol						
Women have lower tolerance to alcohol than men						
Yes (correct) vs No/Don't know	1,06	0,88-1,29	0,515	1,10	0,92-1,31	0,314
It takes about 30 minutes to eliminate from the body the alcohol contained in a can of strong beer						
No (correct) vs Yes/Don't know	1,23	0,92-1,65	0,164	1,11	0,87-1,41	0,407
Correct answers						
1/2 correct answers vs 0	1,11	0,91-1,34	0,296	1,11	0,93-1,34	0,248
Knowledge on marijuana						
Smoking marijuana does not cause physical dependence						
No (correct) vs Yes/Don't know	1,19	0,99-1,44	0,065	1,09	0,91-1,30	0,355
High consumption of marijuana decreases sexual hormones						
Yes (correct) vs No/Don't know	1,60	1,32-1,93	0,000	1,81	0,99-1,41	0,067
Correct answers						
1/2 correct answers vs 0	1,52	1,25-1,84	0,000	1,22	1,02-1,47	0,032

Table 13. Unadjusted Odds Ratios of attitudes, beliefs, risk perceptions, self-esteem, skills, class climate and perception of peers' prevalence at follow-up, intervention vs control pupils, by age

Oucomes	10-14 years old (N=1890)			15-20 years old (N=2125)		
	Crude OR	95% CI	P value	Crude OR	95% CI	P value
Tobacco						
Positive beliefs						
High vs Middle/Low	1,09	0,85-1,40	0,503	1,14	0,92-1,41	0,228
Negative beliefs						
High vs Middle/Low	1,02	0,84-1,22	0,865	1,19	0,96-1,43	0,056
Alcohol						
Positive beliefs						
High vs Middle/Low	1,10	0,86-1,40	0,461	1,18	0,96-1,46	0,117
Negative beliefs						
High vs Middle/Low	1,18	0,98-1,43	0,077	1,25	1,04-1,50	0,015
Marijuana and other drugs						
Positive beliefs						
High vs Middle/Low	1,07	0,84-1,36	0,600	1,03	0,84-1,28	0,764
Negative beliefs						
High vs Middle/Low	0,96	0,79-1,17	0,664	0,98	0,82-1,17	0,794
Attitudes towards drugs						
Positive attitudes						
Middle/High vs Low	1.14	0.91-1.44	0.246	0.94	0.78-1.14	0.540
Negative attitudes						
High vs Middle/Low	0.90	0.74-1.10	0.311	0.91	0.76-1.08	0.274
Self-esteem						
Positive indicator						
High vs Middle/Low	0,81	0,62-1,04	0,098	0,91	0,73-1,13	0,380
Negative indicator						
Middle/High vs Low	1,03	0,83-1,29	0,767	0,82	0,65-1,02	0,074
Decision making skills						
Positive indicator						
High vs Middle/Low	0,97	0,80-1,16	0,716	1,14	0,95-1,36	0,148
Negative indicator						
Middle/High vs Low	1,08	0,88-1,32	0,468	0,95	0,78-1,16	0,621
Intention to refuse an offer of a friend of						
Cigarettes						
High vs Low	0,87	0,59-1,29	0,500	0,95	0,73-1,23	0,687
Alcohol						
High vs Low	0,89	0,70-1,11	0,298	1,05	0,85-1,31	0,631
Cannabis						
High vs Low	0,92	0,68-1,25	0,593	0,83	0,65-1,06	0,139
Any substance						
High vs Low	0,94	0,71-1,24	0,647	1,02	0,81-1,28	0,881
Communication skills						
High vs Middle/Low	0,89	0,73-1,09	0,272	0,84	0,69-1,03	0,096
Class climate						
Good vs Medium/Bad	1.46	1.17-1.83	0.001	1.17	0.93-1.46	0.177
Peers' prevalence						
none/less than half/about half smoke cigarettes	1.39	1.14-1.70	0.001	1.14	0.95-1.38	0.162
none/less than half/about half drink alcohol	1.25	1.03-1.52	0.022	1.12	0.94-1.35	0.212
none/less than half/about half get drunk	1.26	1.03-1.53	0.023	1.17	0.96-1.41	0.116
none/less than half/about half use marijuana or other drugs	1.10	0.91-1.36	0.331	1.12	0.93-1.35	0.223

*vs more than half/all of them/don't know

4. Effectiveness analyses: matched sample follow-up vs baseline

4.1. Sample and rationale for the analysis

As shown in Table 1, the matched sample included **3342** pupils for whom the baseline questionnaire matched with the follow-up questionnaire through the anonymous code.
This sample was 14% lower than that needed for the study to reach statistical significance, and there was differential drop-out by arm: 1384 intervention pupils were only 71% of those needed according to sample size calculations (29% drop-out), whilst 1958 control pupils were a little more than those needed (0% drop-out).
However, **the matched sample is more reliable than the overall follow-up sample** for several reasons. First, the low matching rate suggested that in the intervention group different pupils participated in the baseline and in the follow-up surveys, so that we can't be sure that not matching pupils participating in the follow-up survey (that are included in the follow-up sample but not in the matched sample) were in the class for the entire year and received the program. Second, the matched database included the information on each variable at baseline, and at follow-up, so the baseline level of the indicator could be taken into account to estimate the net effect of the program, and the changes between baseline and follow-up could be studied.
So, the analysis of the matched sample must be considered more reliable than that of the follow-up-only sample in estimating the effect of the program.

4.2. Follow-up vs baseline changes

In the next graphs, the changes of the indicators from baseline to follow-up in the intervention and control arms are shown.
It appears that the **perception of good class climate improved among intervention and decreased among control pupils** (Figure 1).
As regards use of substances, no effect of the intervention was observed for indicators of cigarettes (Figure 2), and alcohol (Figure 5) use at least once in the last 30 days, drunkenness episodes (Figure 8 and Figure 9) and use of other illicit drugs (Figure 12 and Figure 13).
A possible effect of the intervention was detected on the following indicators:

- use of cigarettes regularly: more than 6 times in the last 30 days (Figure 3)
- use of cigarettes daily: more than 20 times in the last 30 days (Figure 4)
- use of alcohol regularly: more than 6 times in the last 30 days (Figure 6)
- use of alcohol daily: more than 20 times in the last 30 days (Figure 7)
- use of marijuana at least once in the last 30 days (Figure 10)
- use of marijuana regularly: more than 3 times in the last 30 days (Figure 11).

A possible effect of the intervention was observed also for **all the indicators of peers' prevalence**: for these indicators, the proportion of pupils who perceived as "low" the prevalence of use among peers at follow-up was higher among intervention vs control pupils (Figure 14, 15, 16, 17); on the contrary, only a slight effect of the program was detected on the perception of friends using substances (Figure 18, 19, 20, 21).

Negative beliefs were higher among intervention pupils for all substances (cigarettes, alcohol and marijuana) whilst were decreased among control pupils (Figure 22, 23, 24).

No consistent improvement of knowledge about tobacco, alcohol and marijuana occurred from baseline to follow-up (Figure 26, 27, 28, 29, 30, 31, 33). However, these data about knowledge were strange and probably not reliable. It is indeed unlikely that the proportion of correct answers reduced from baseline to follow-up.

All these possible effects of the program must be analysed in logistic regression models adjusting for baseline levels and hierarchical structure of the data.

Figure 1.

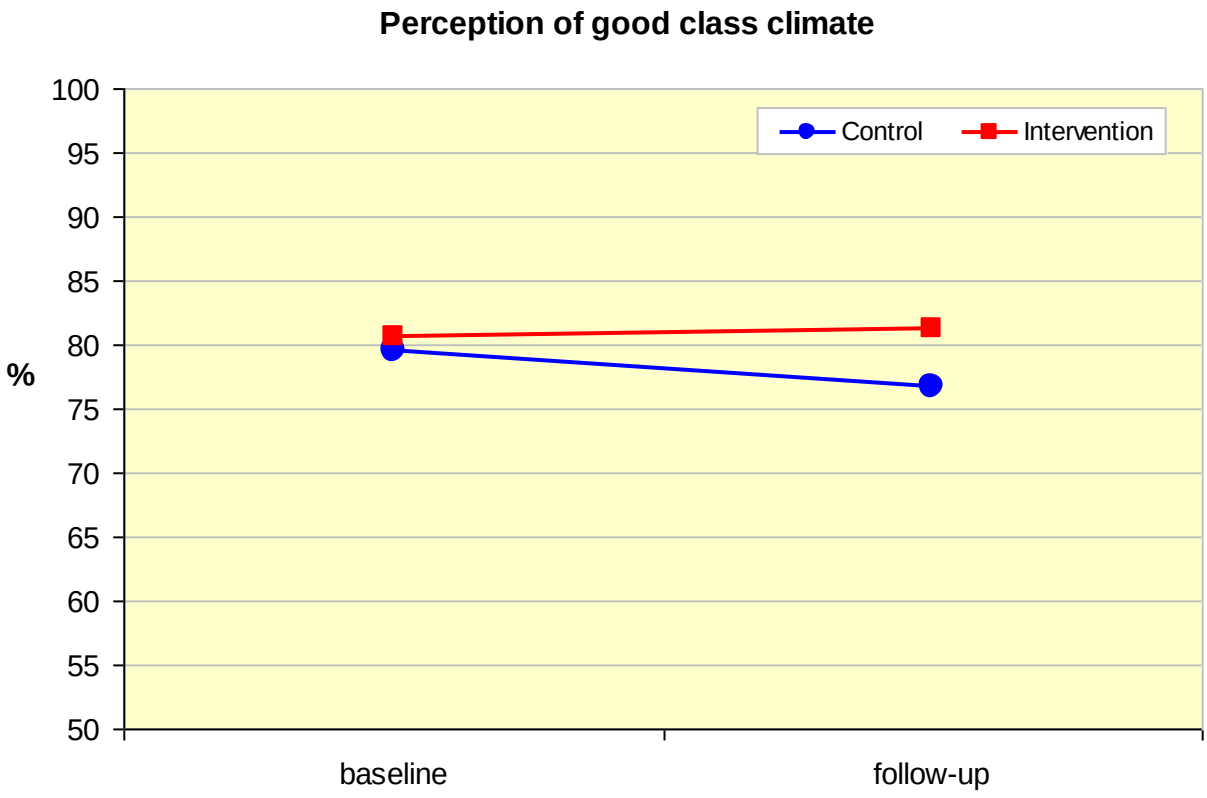


Figure 2.

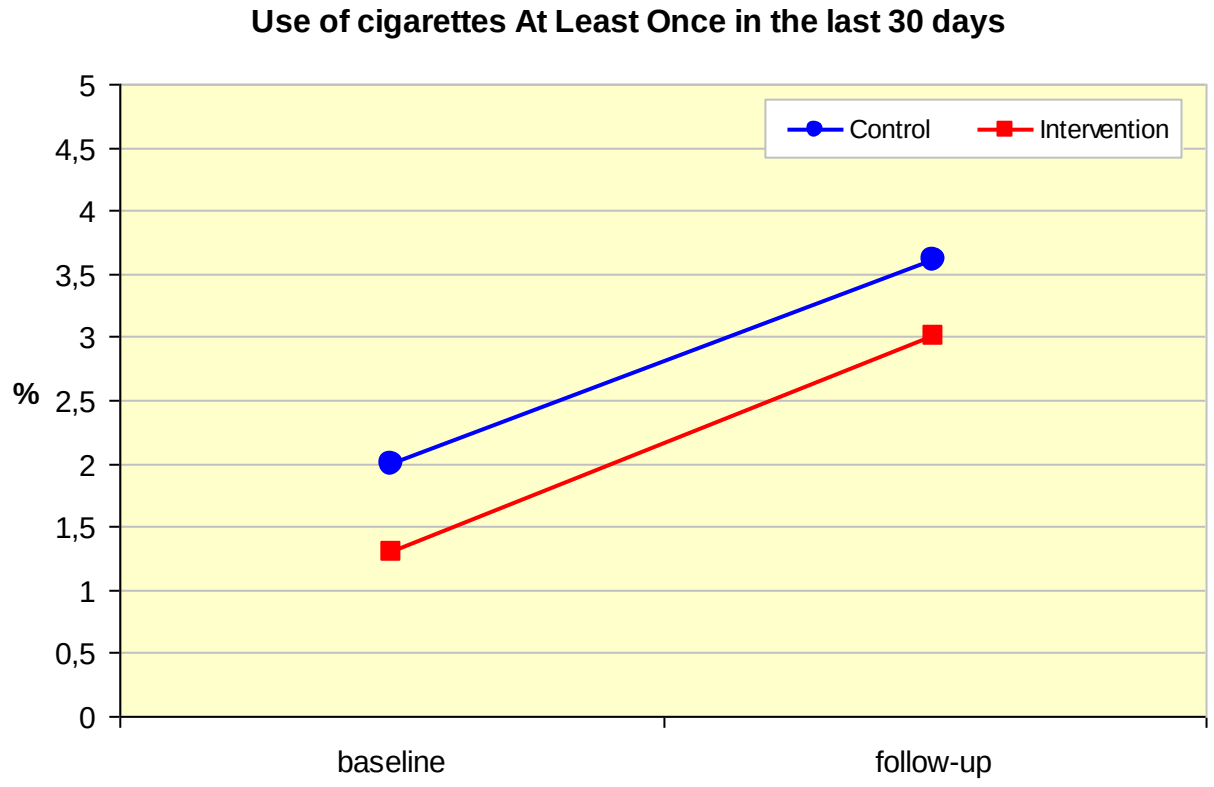


Figure 3.

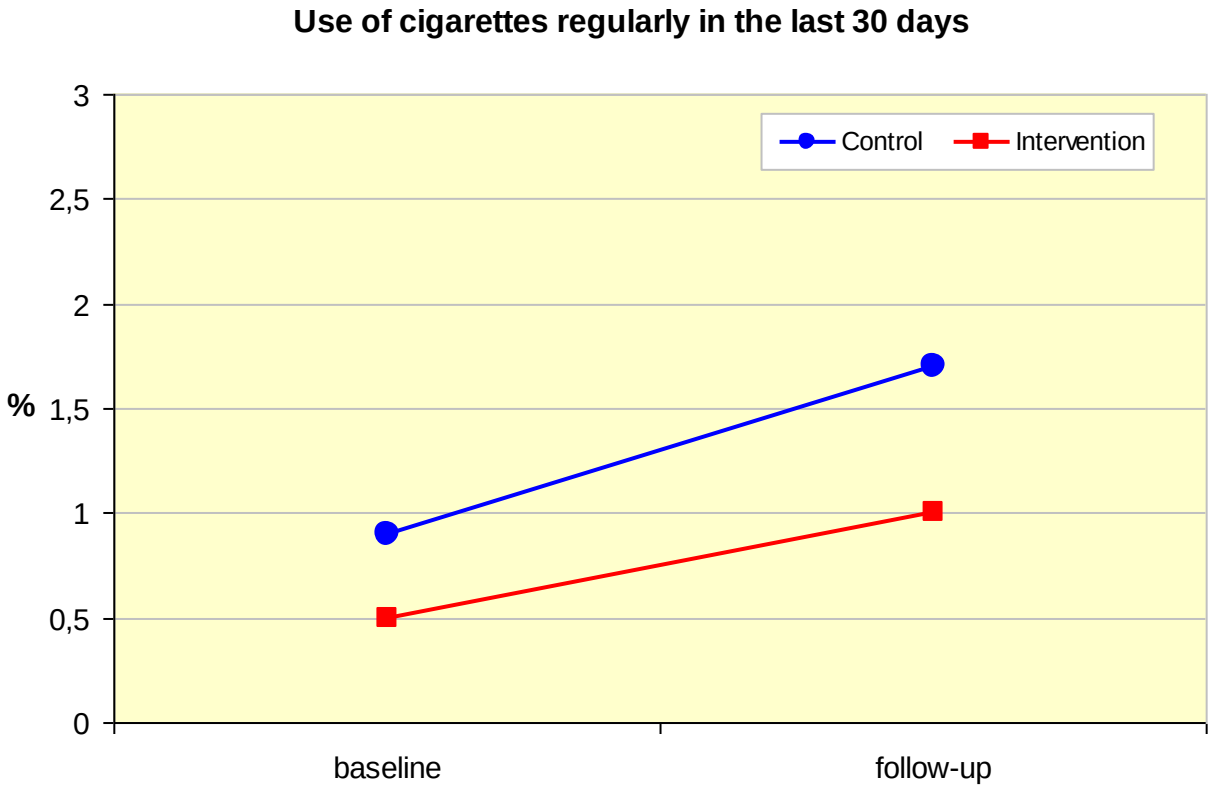


Figure 4.

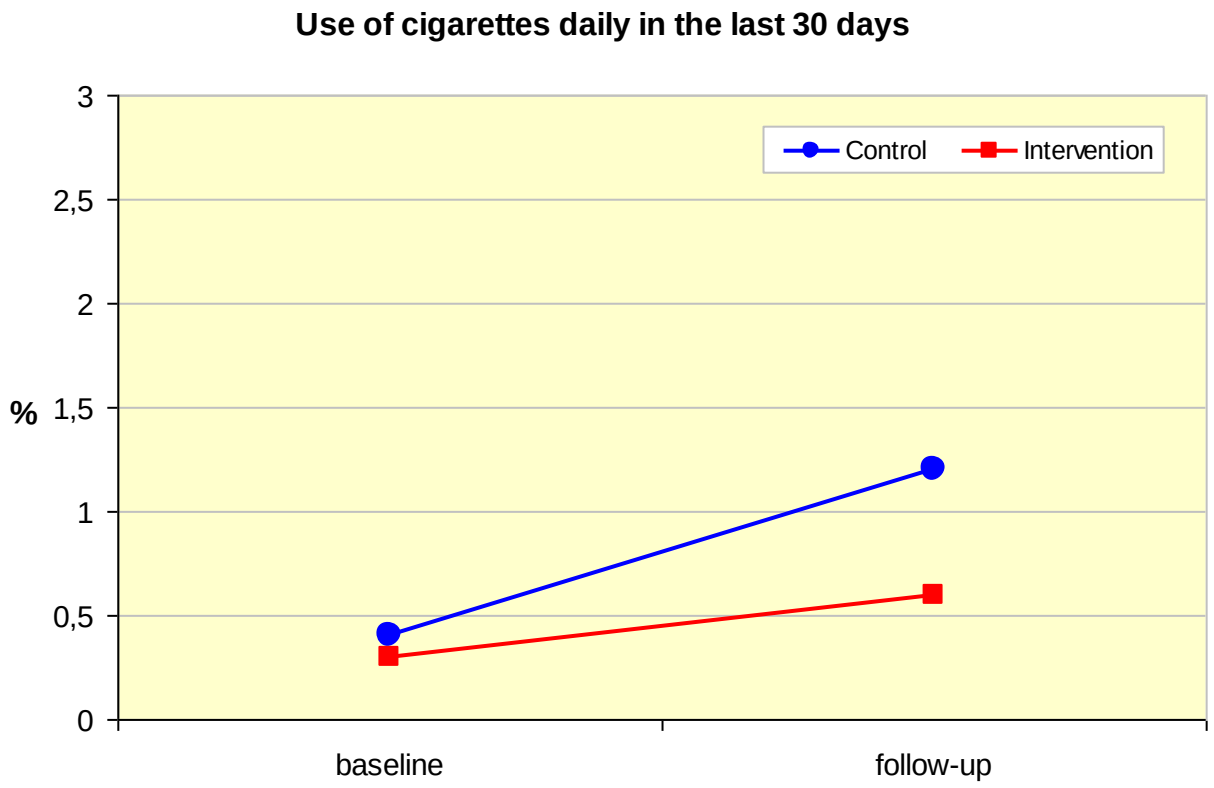


Figure 5.

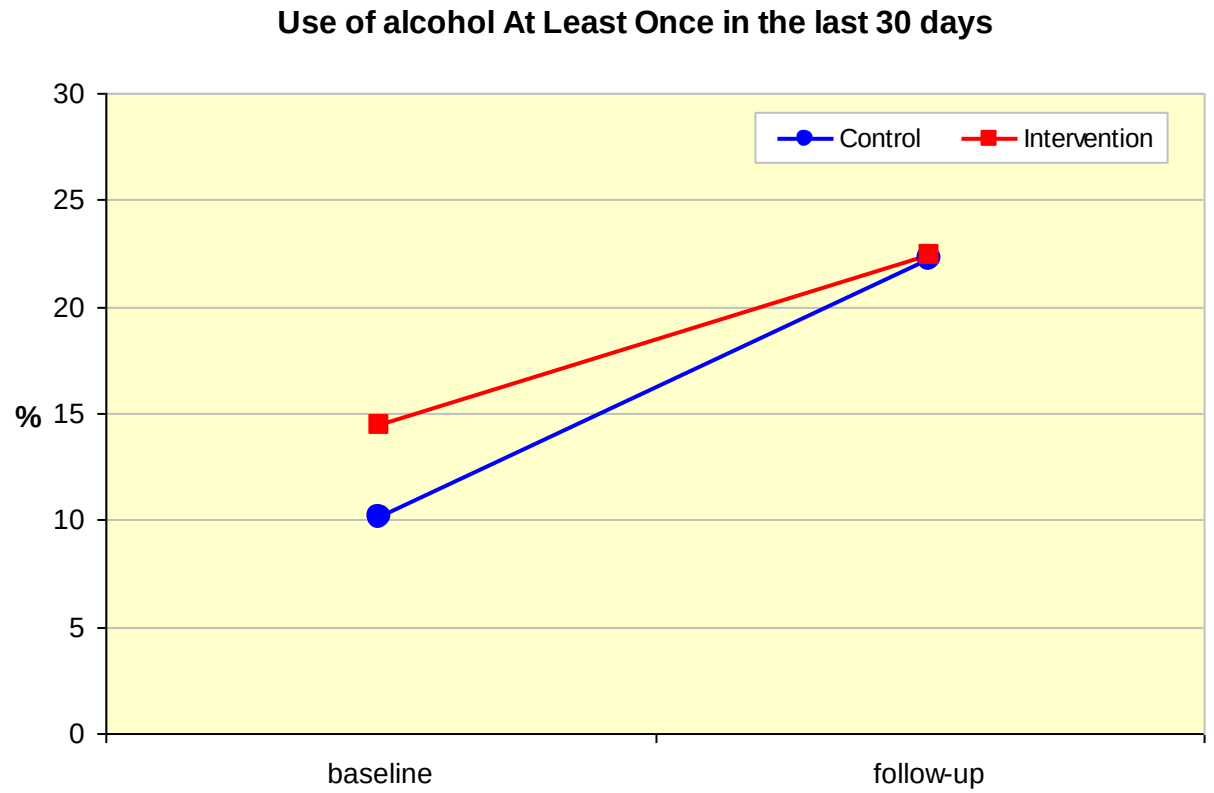


Figure 6.

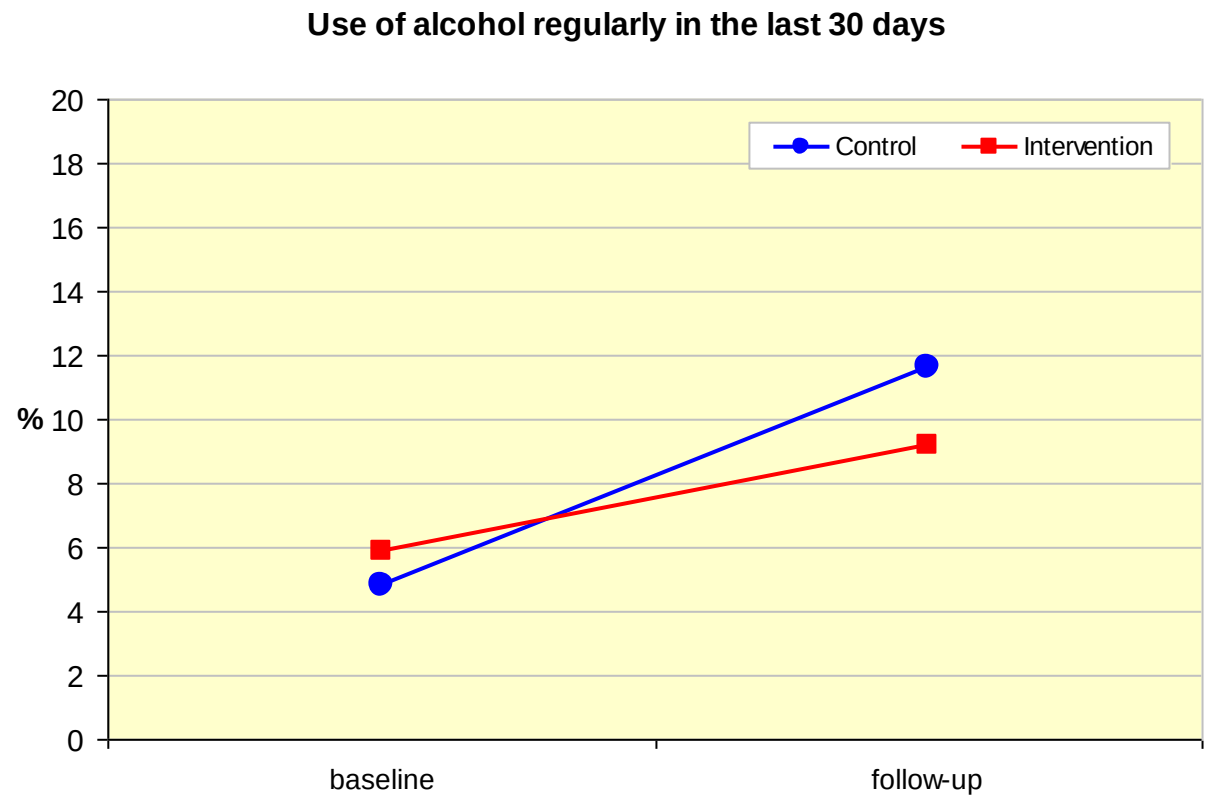


Figure 7.

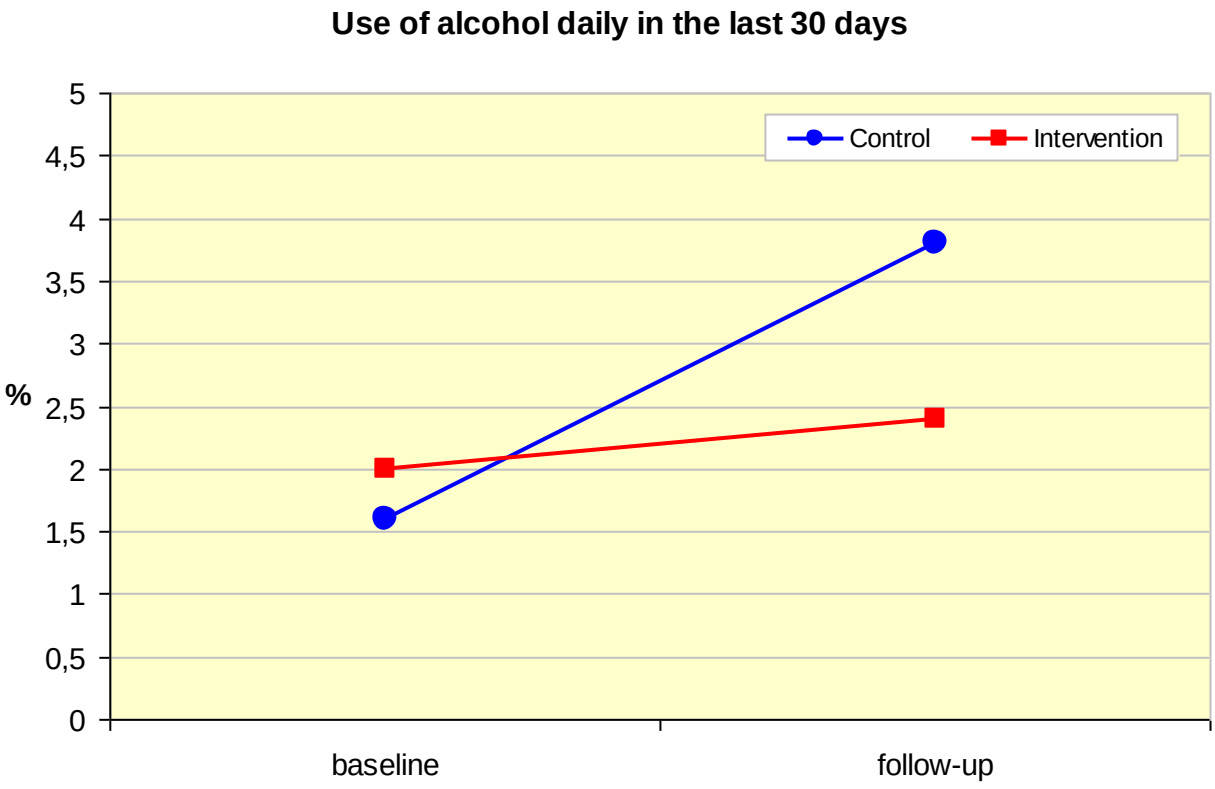


Figure 8.

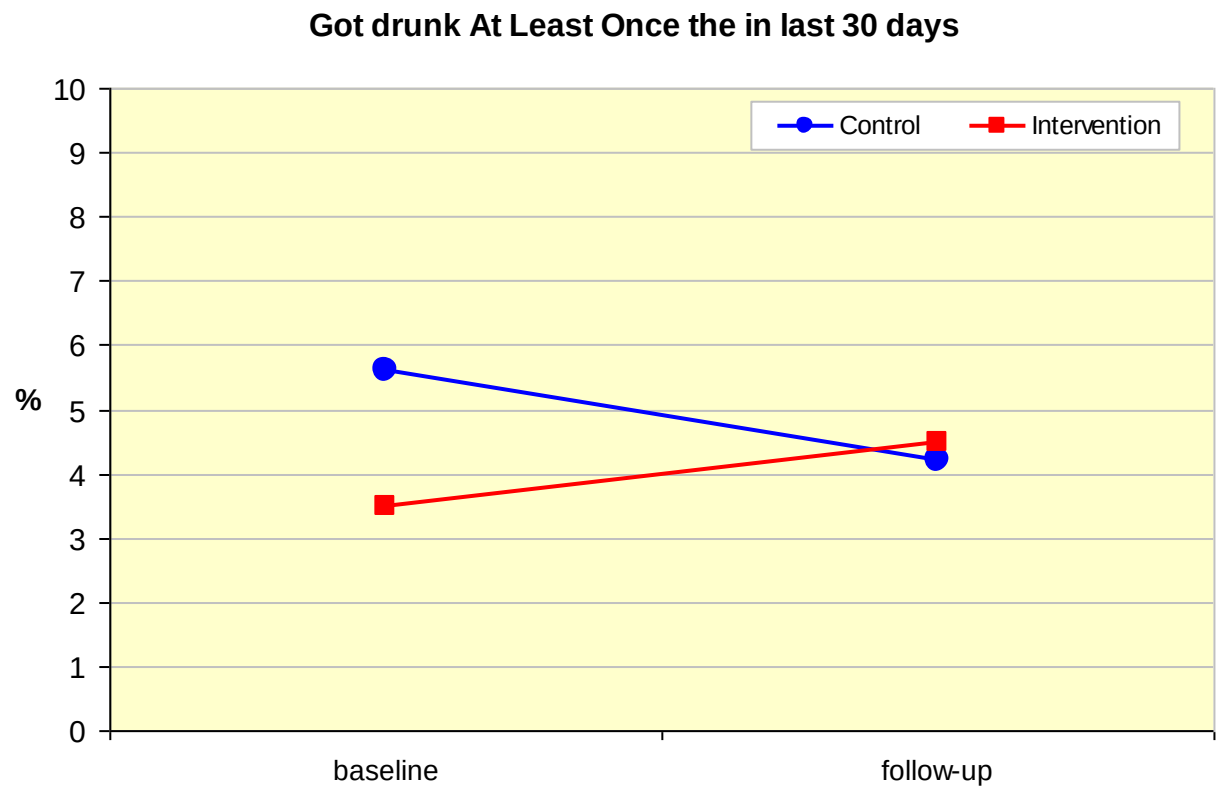


Figure 9.

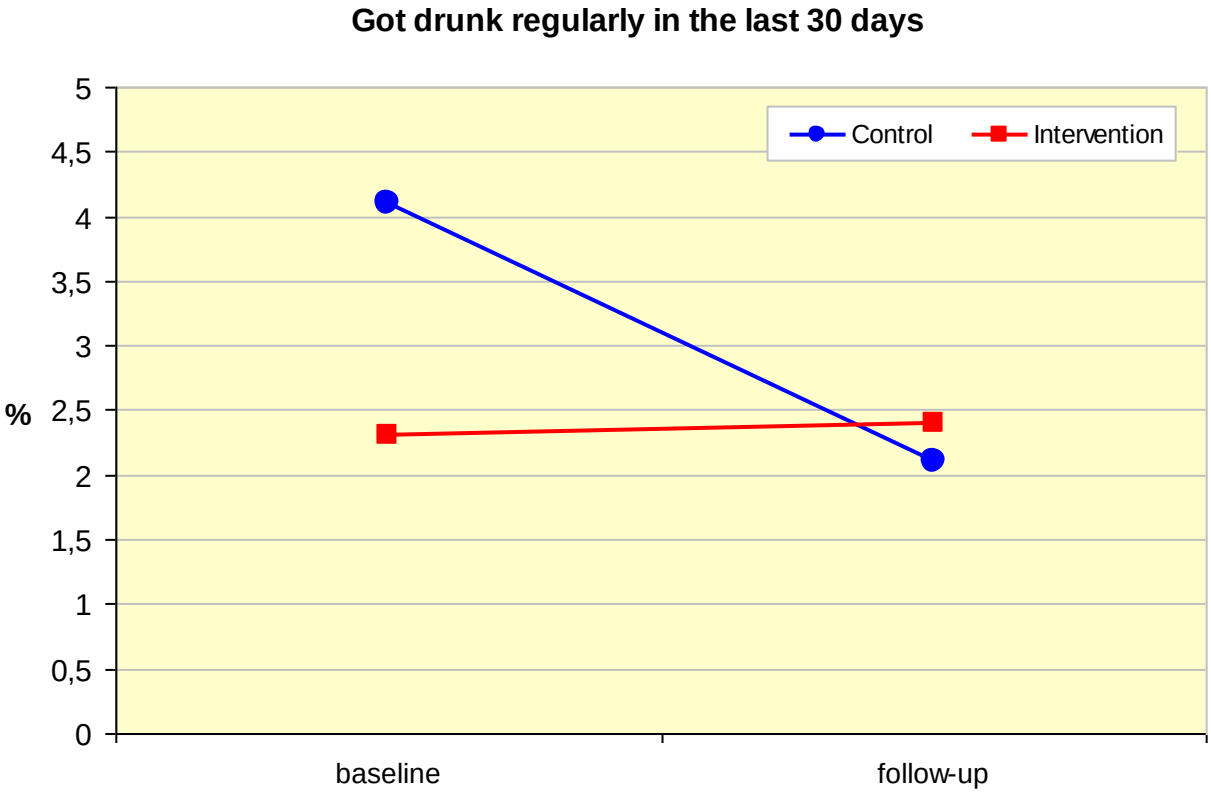


Figure 10.

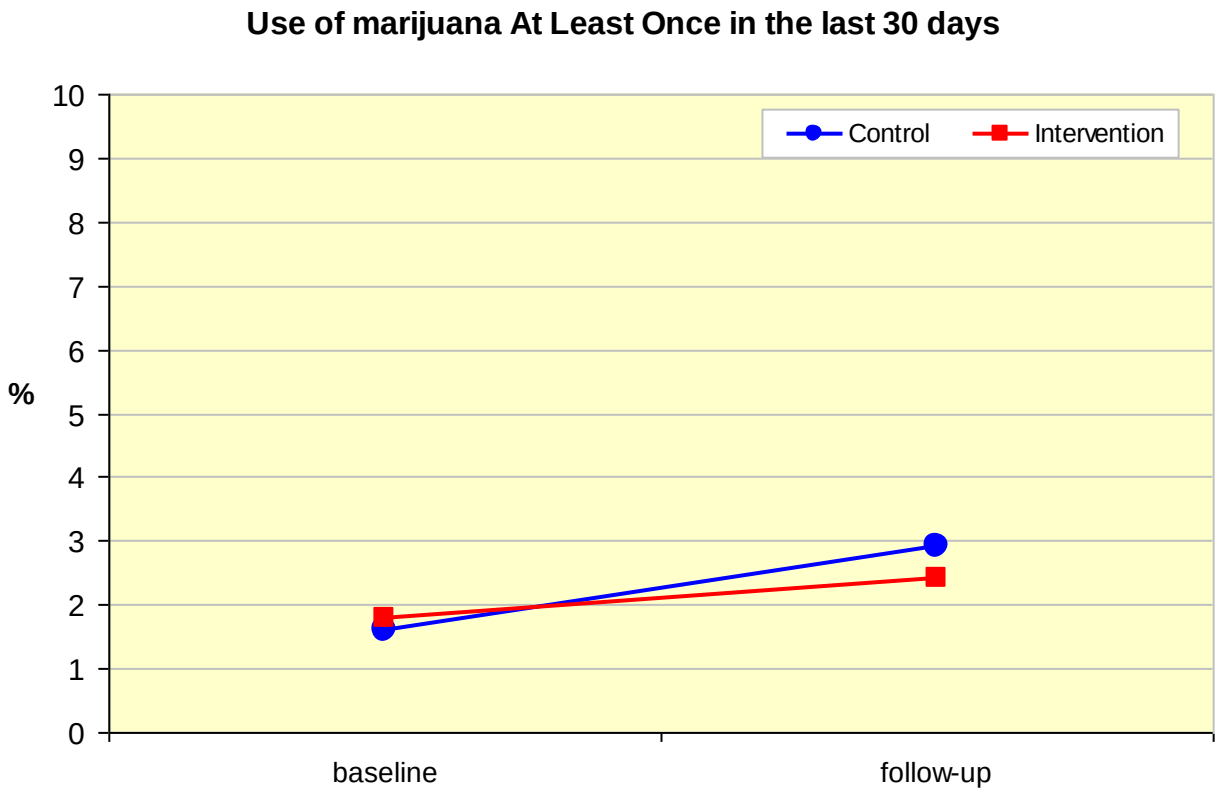


Figure 11.

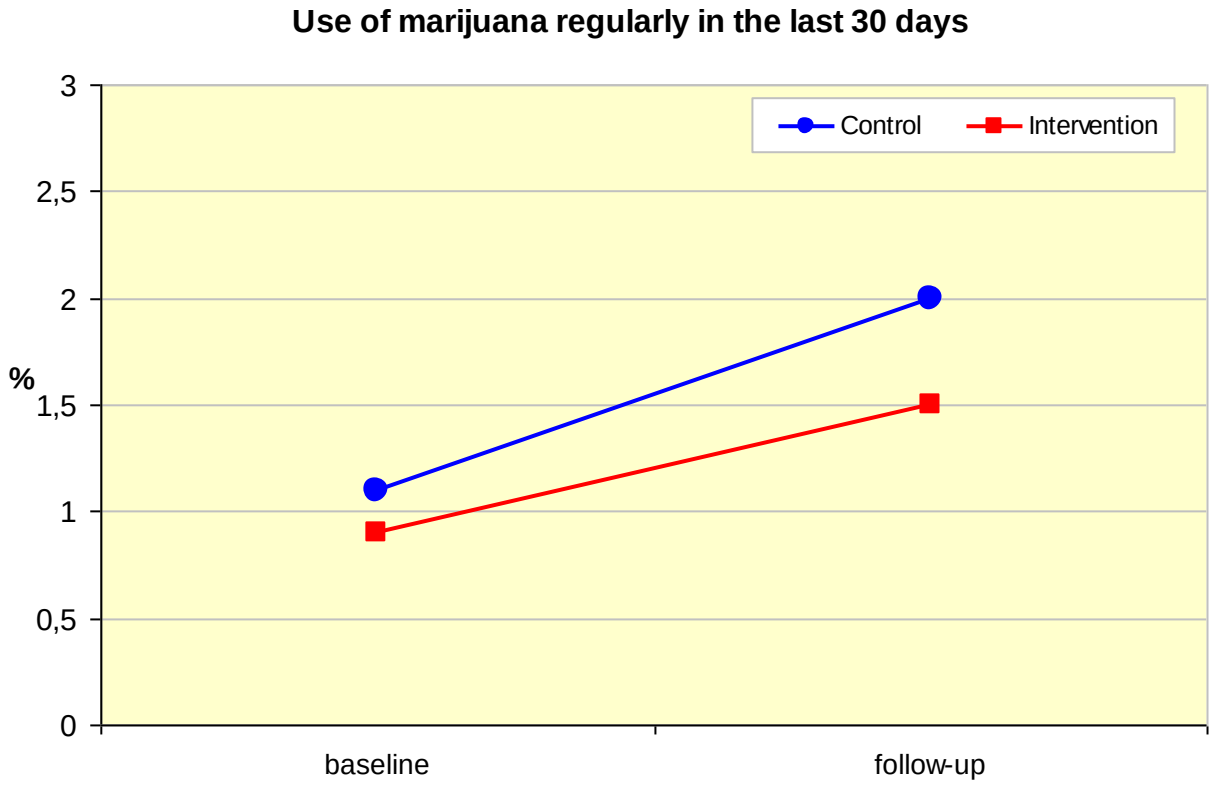


Figure 12.

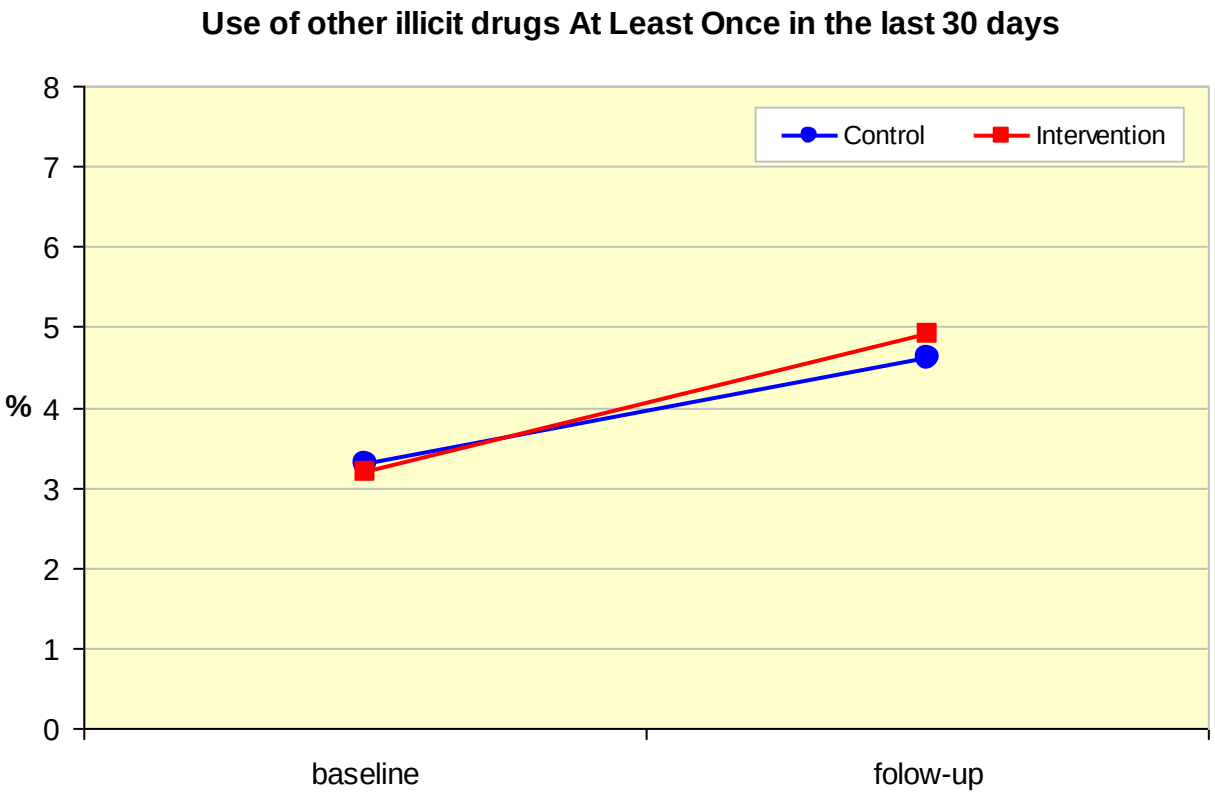


Figure 13.

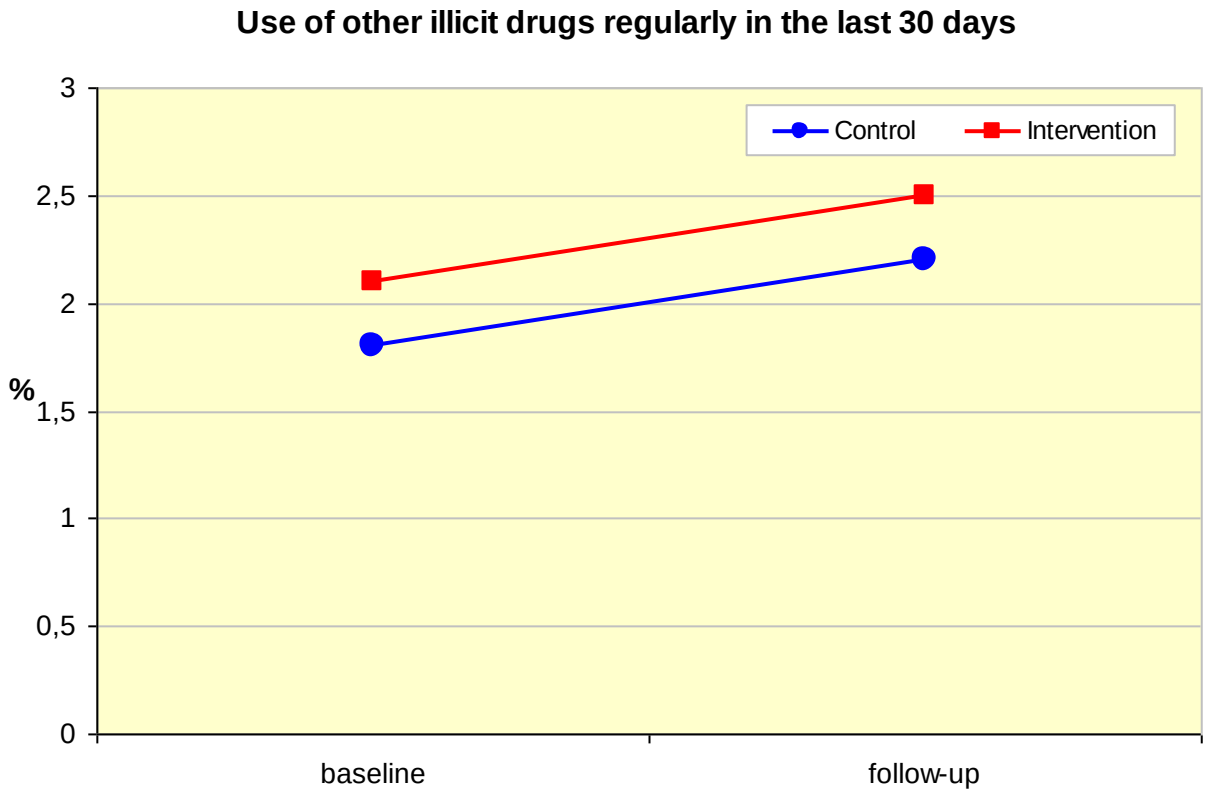


Figure 14.

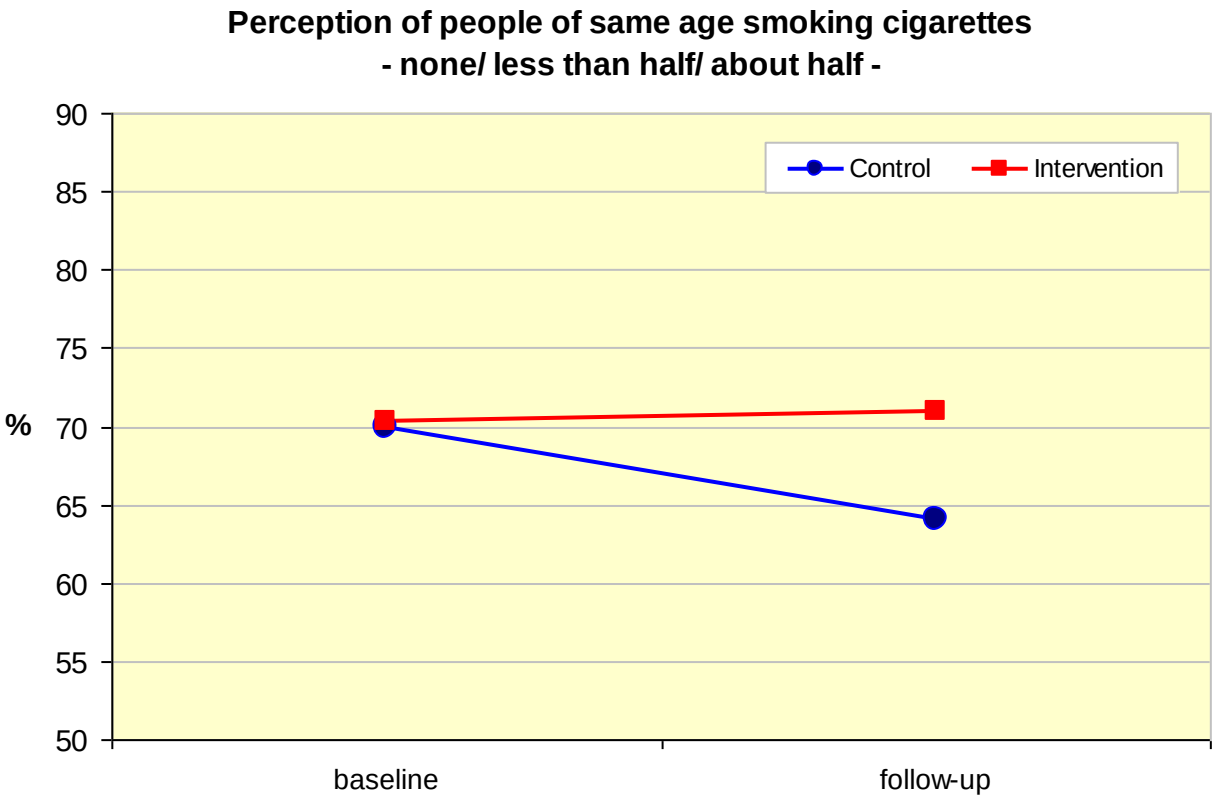


Figure 15.

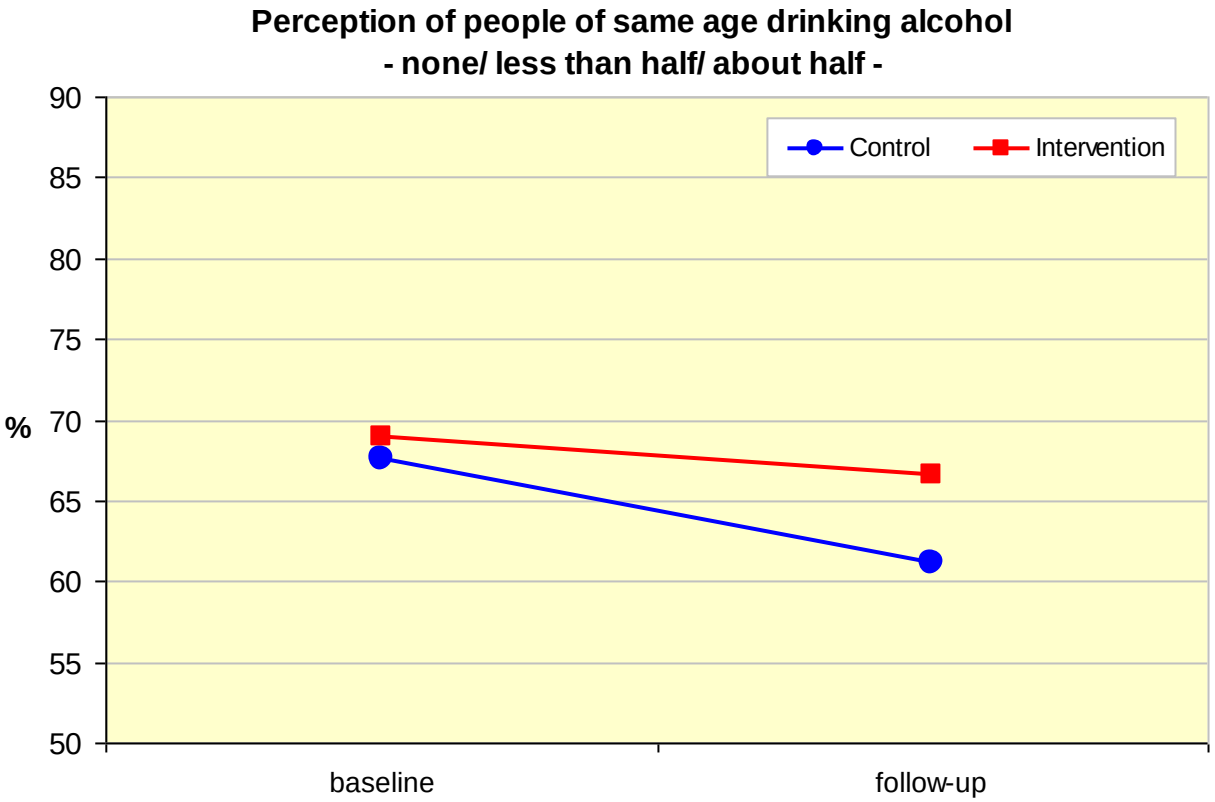


Figure 16.

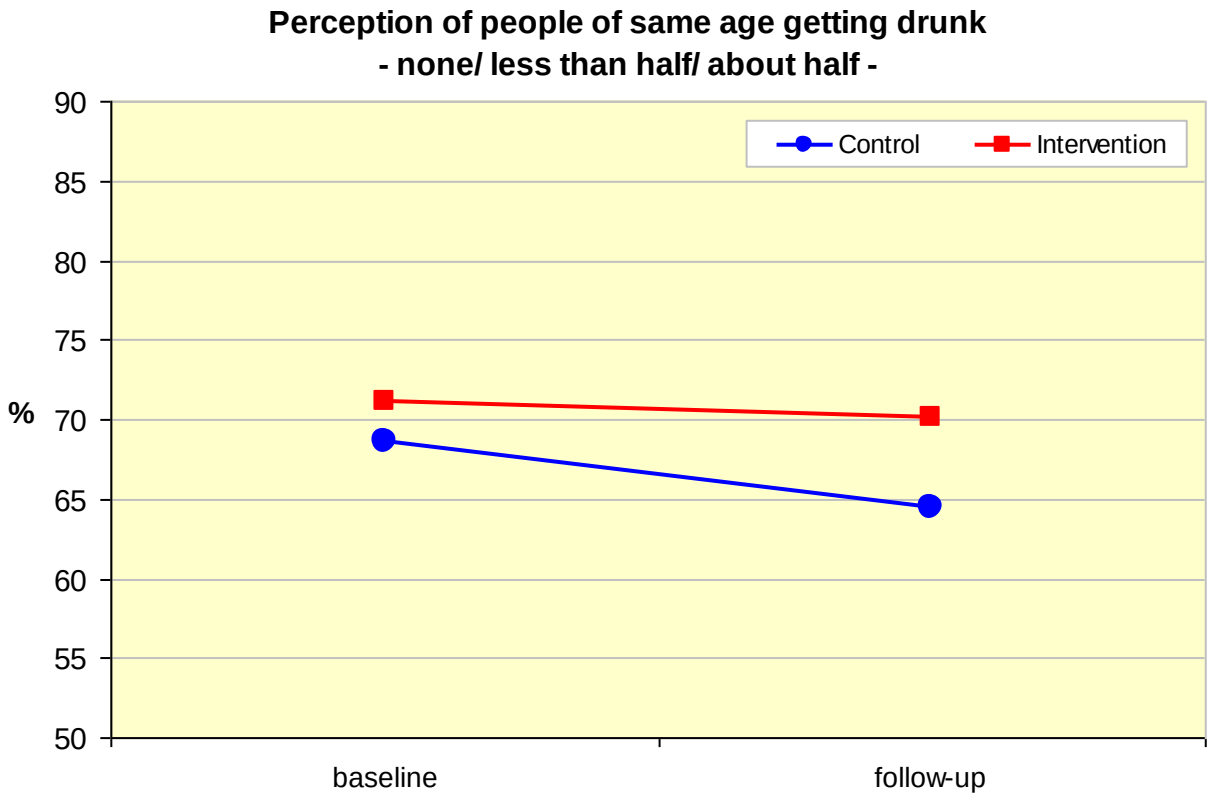
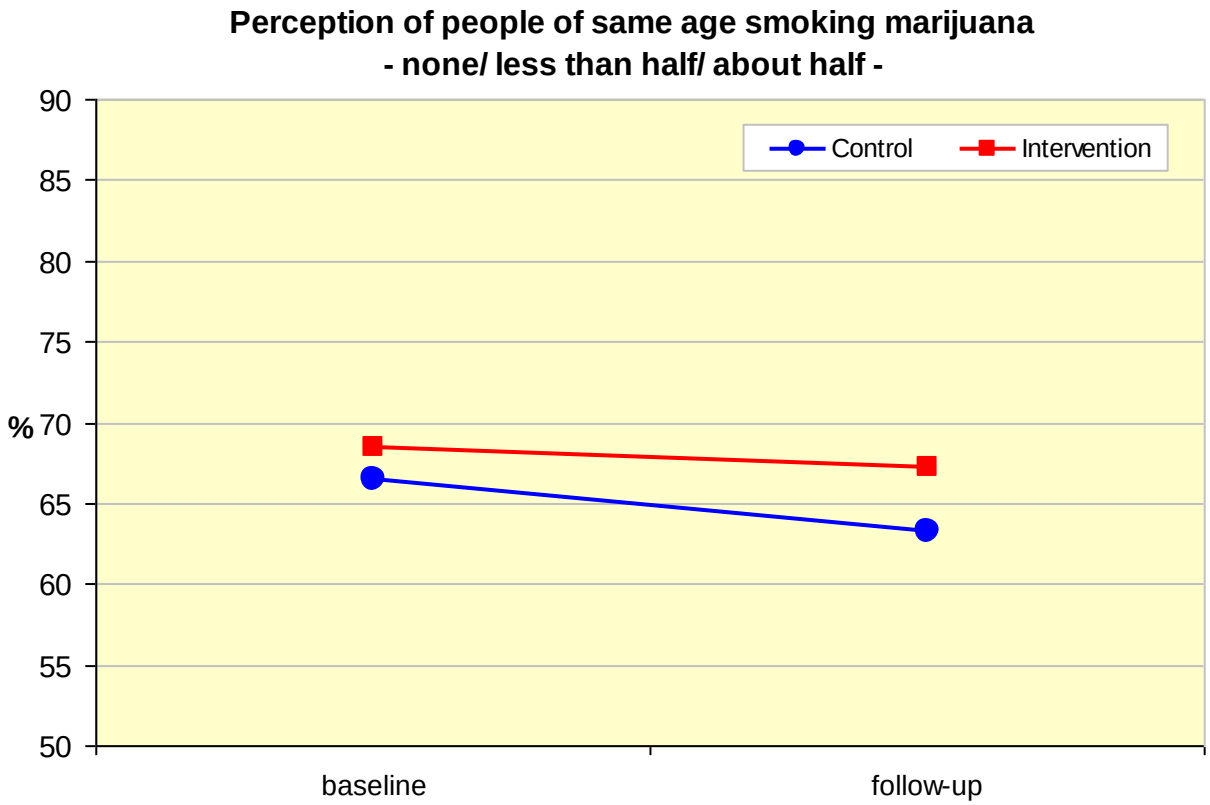


Figure 17.



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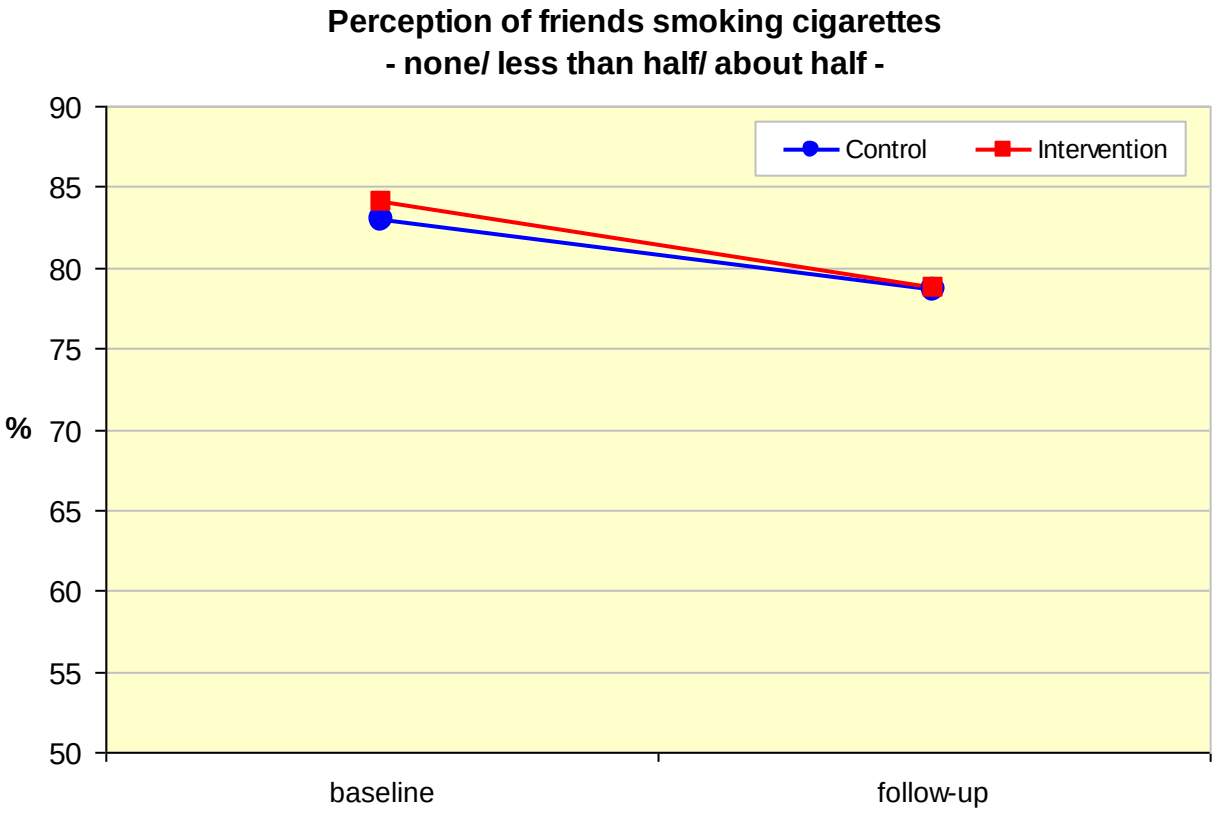

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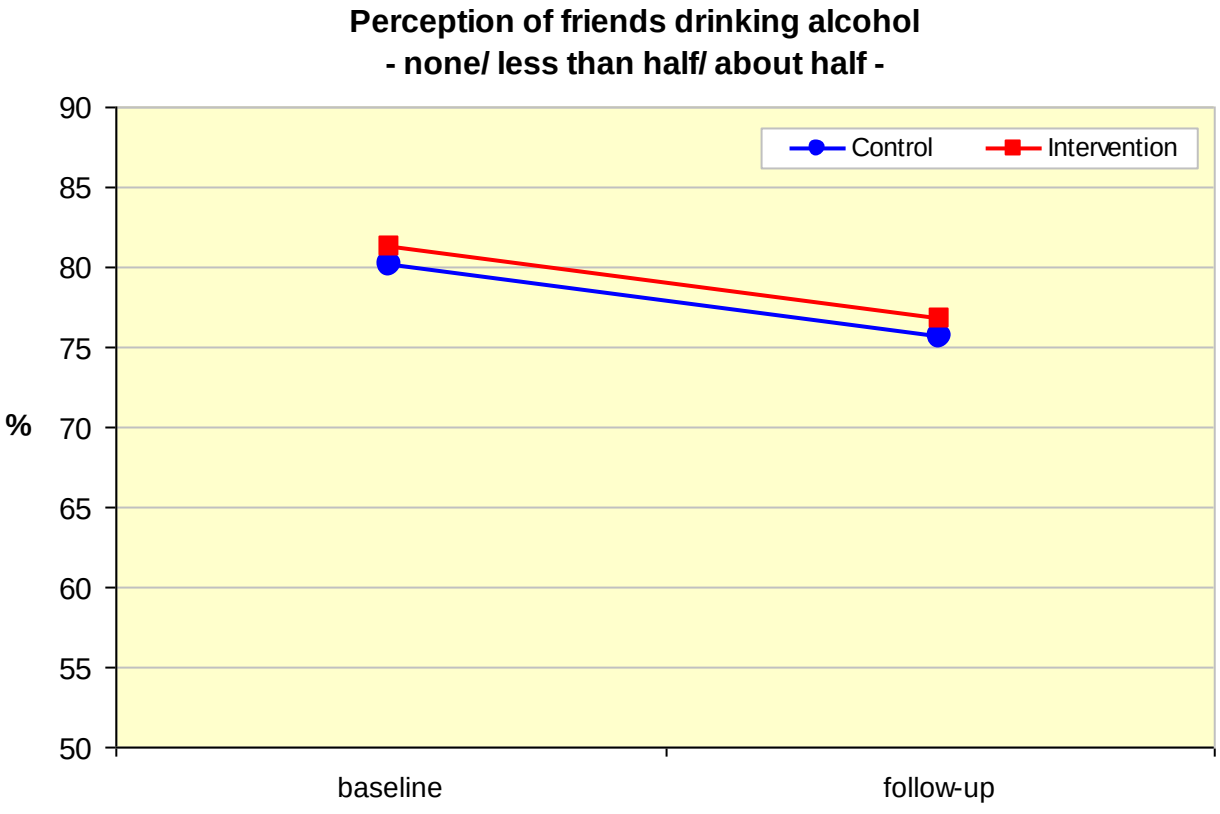

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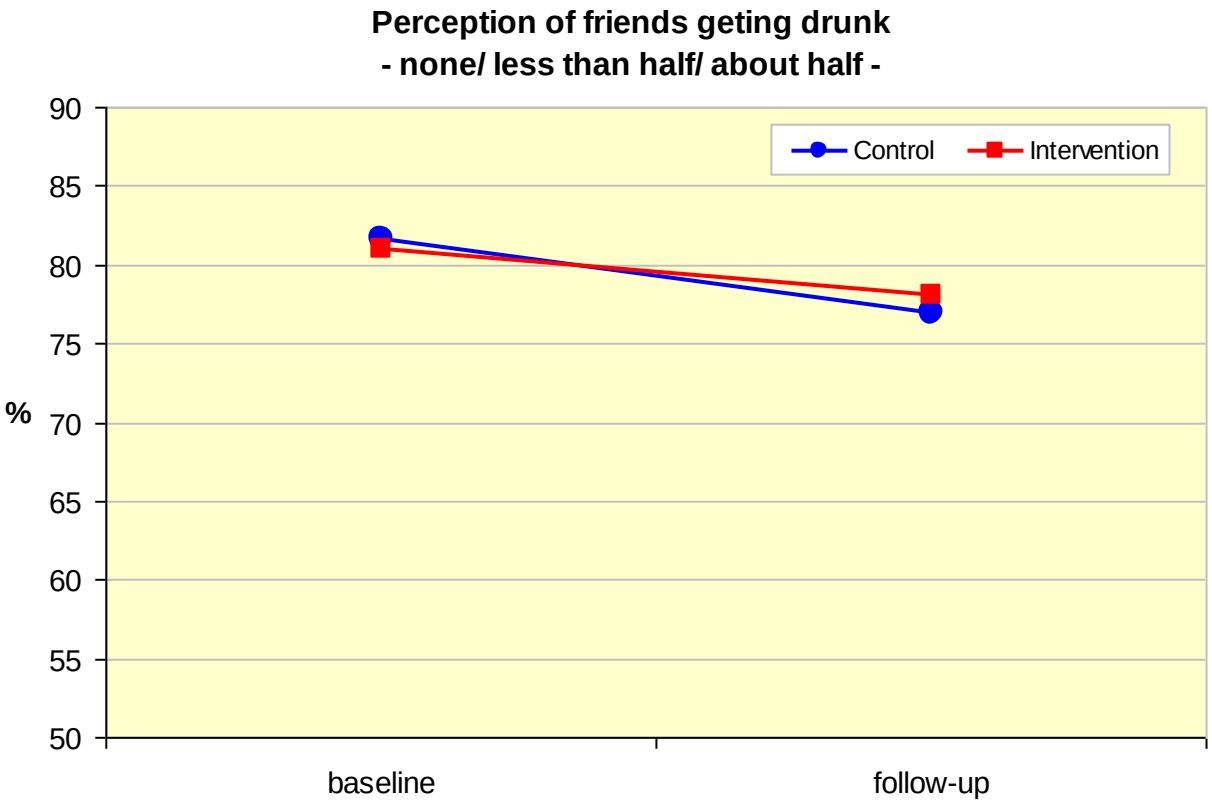

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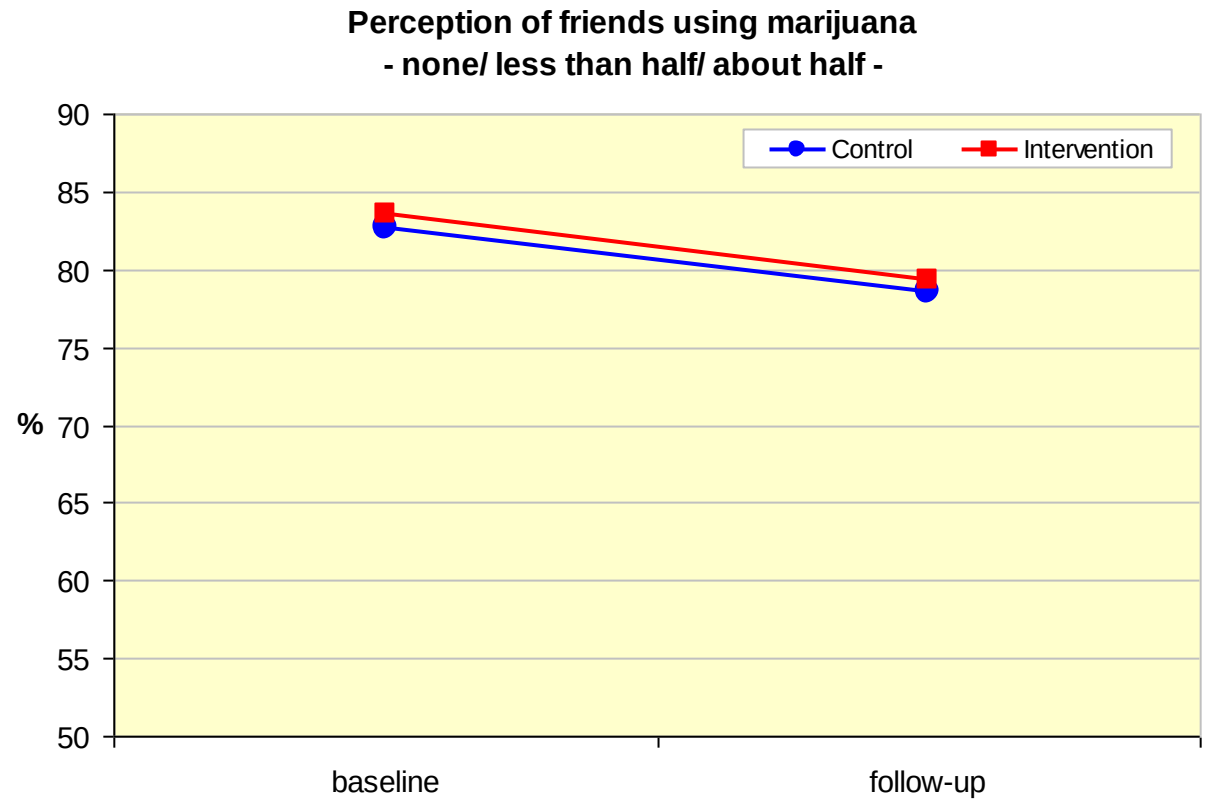

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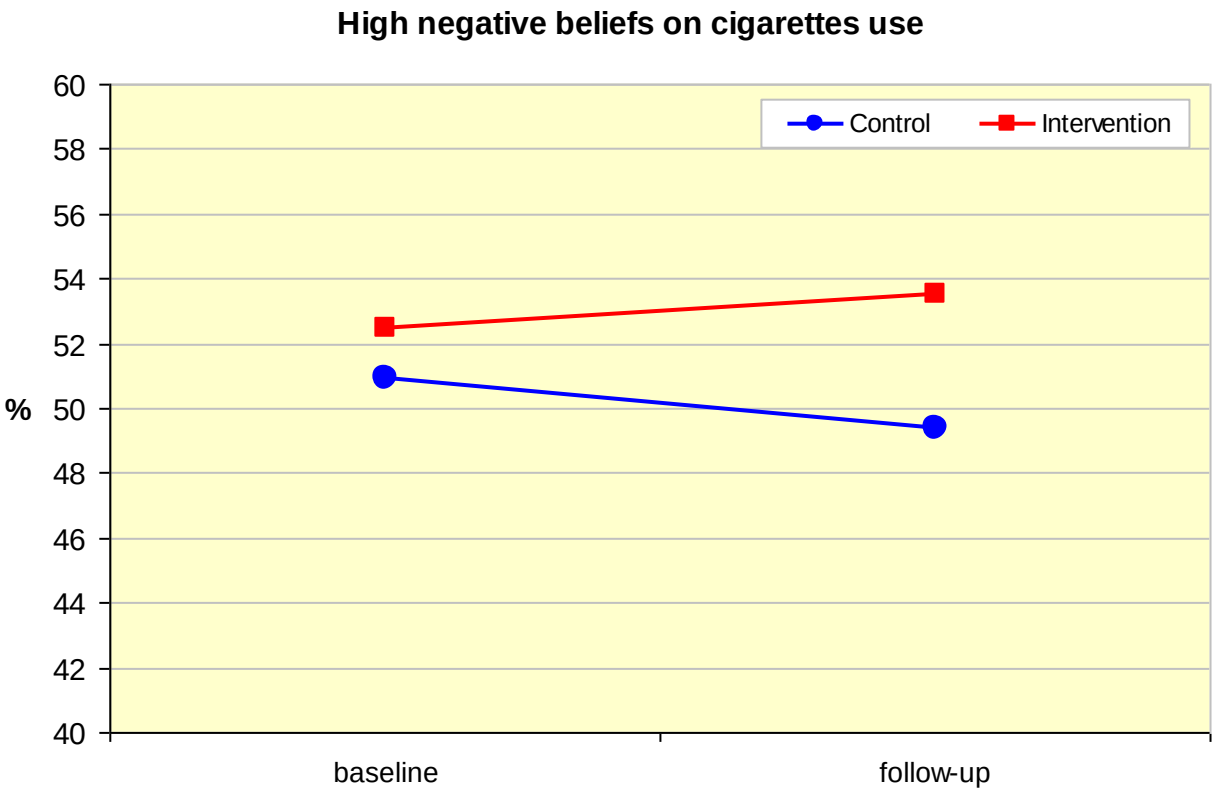

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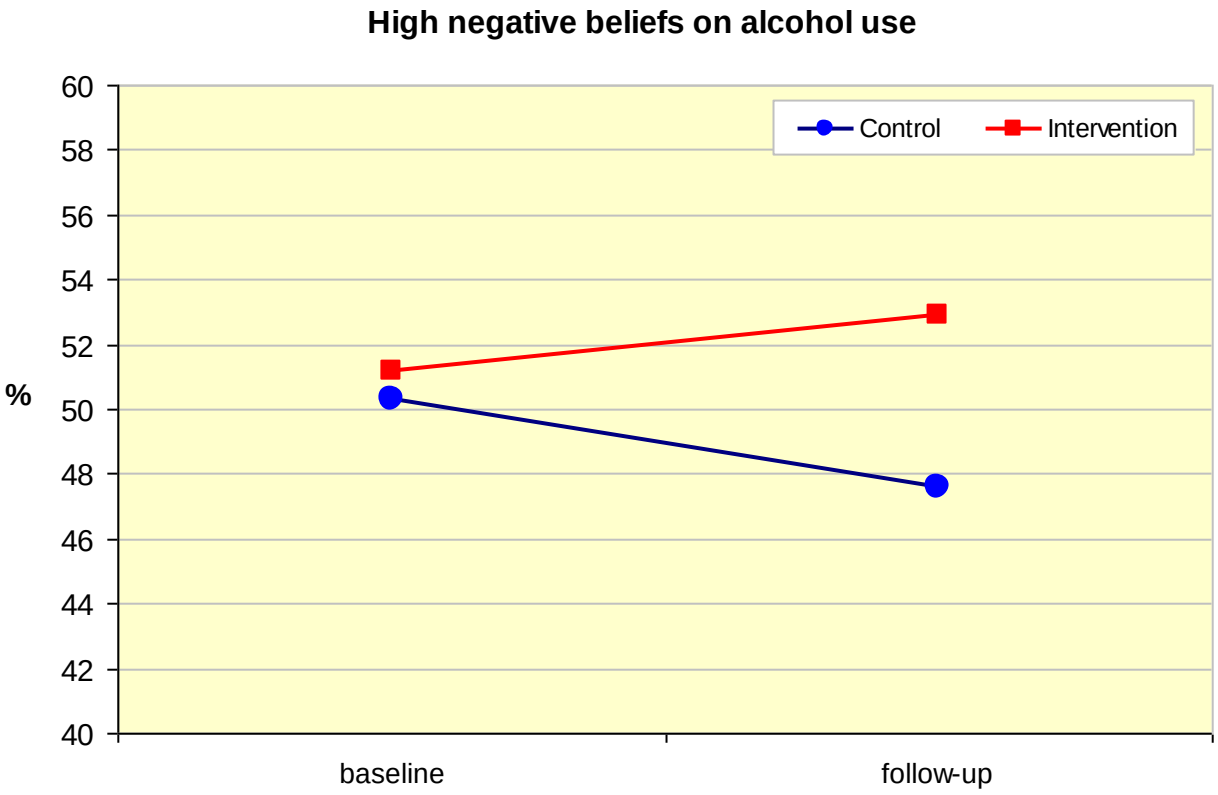

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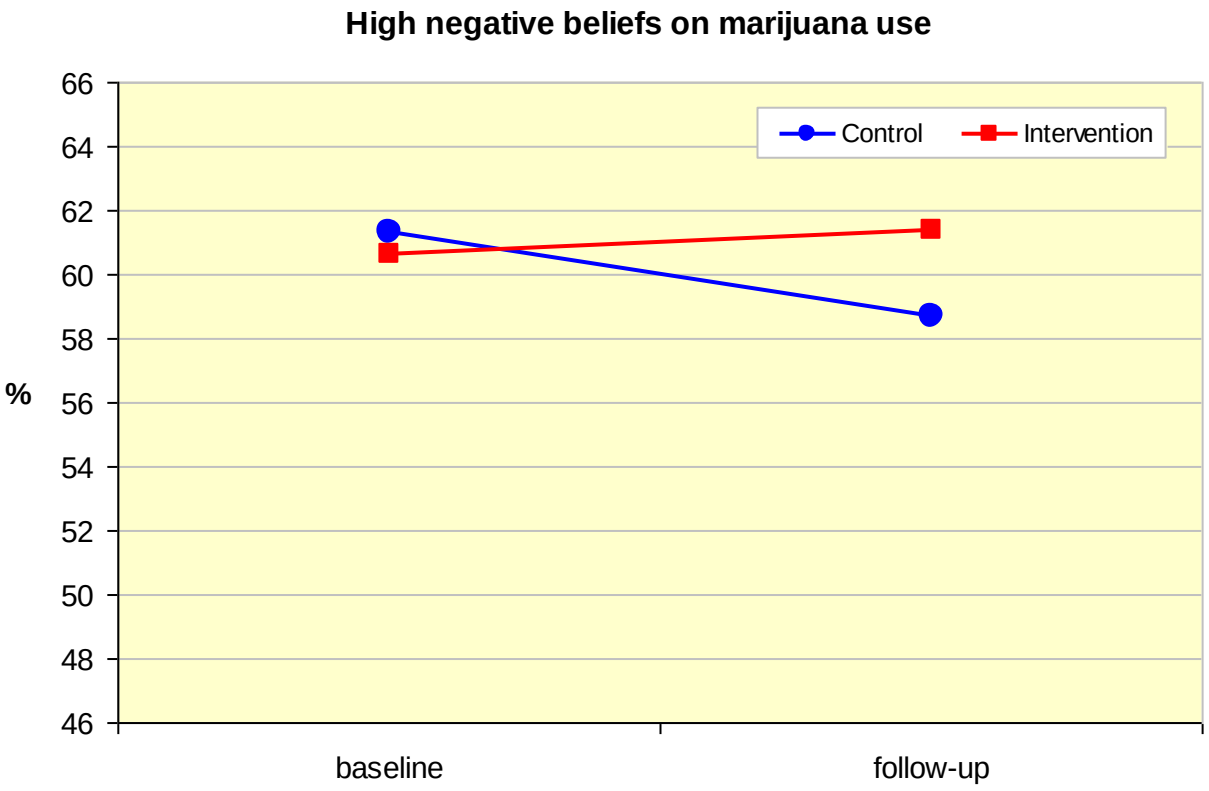

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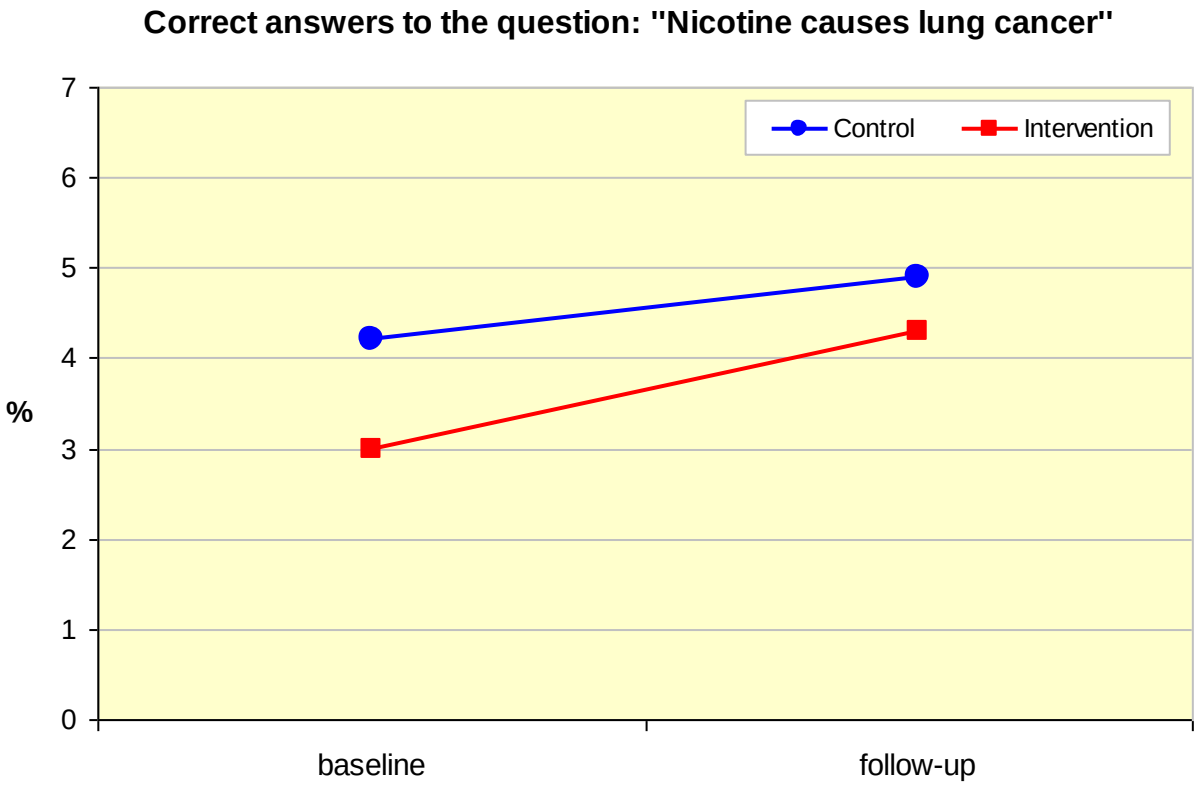

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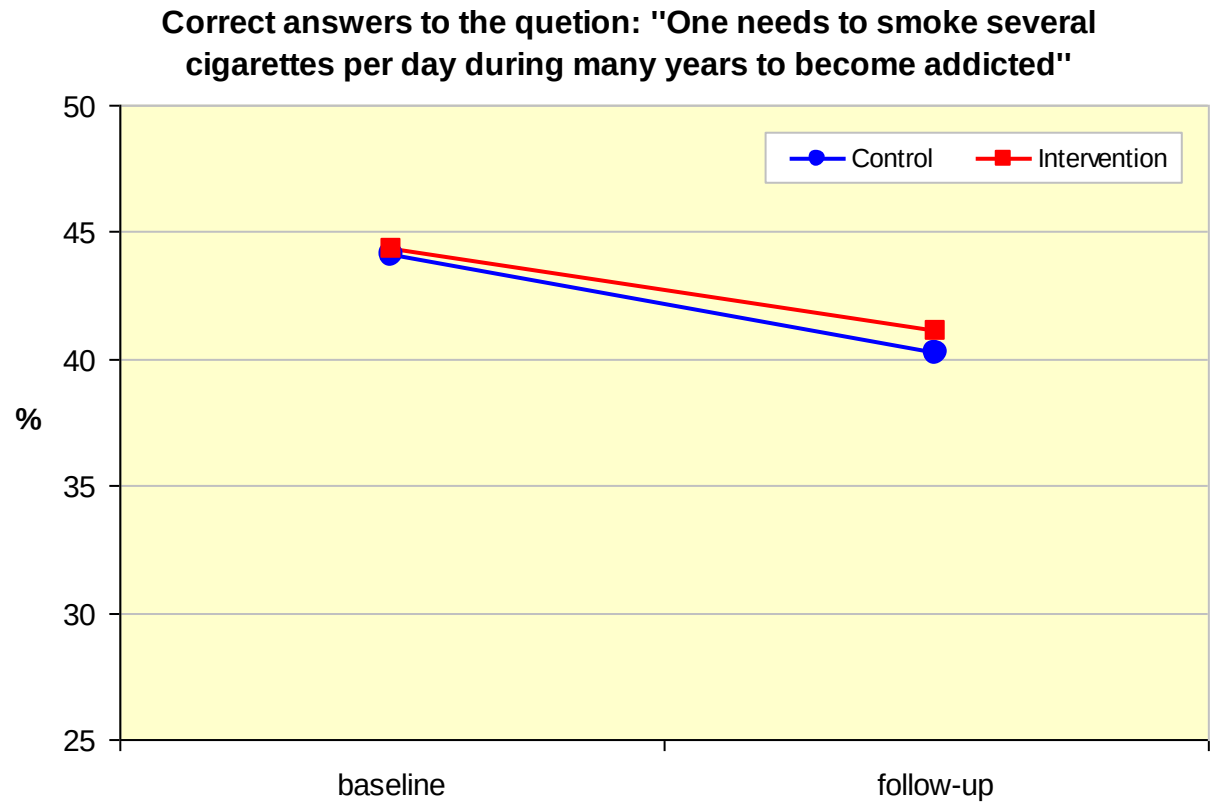

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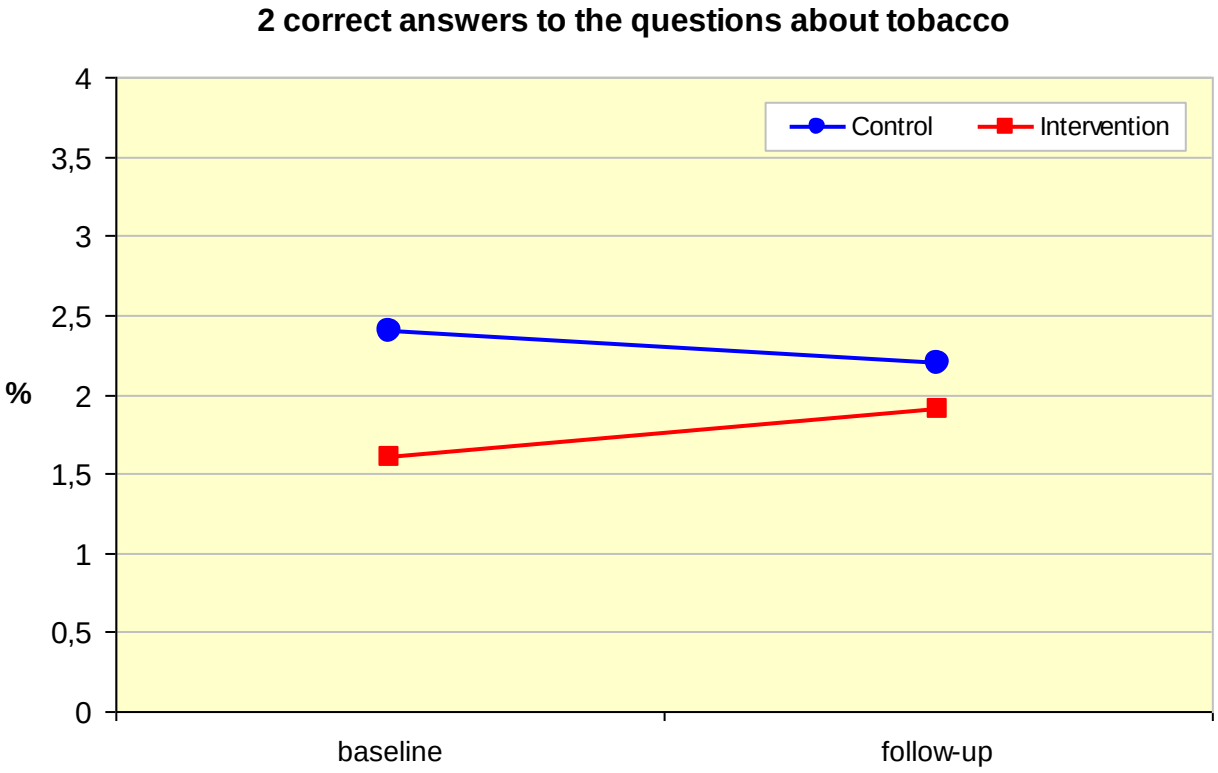

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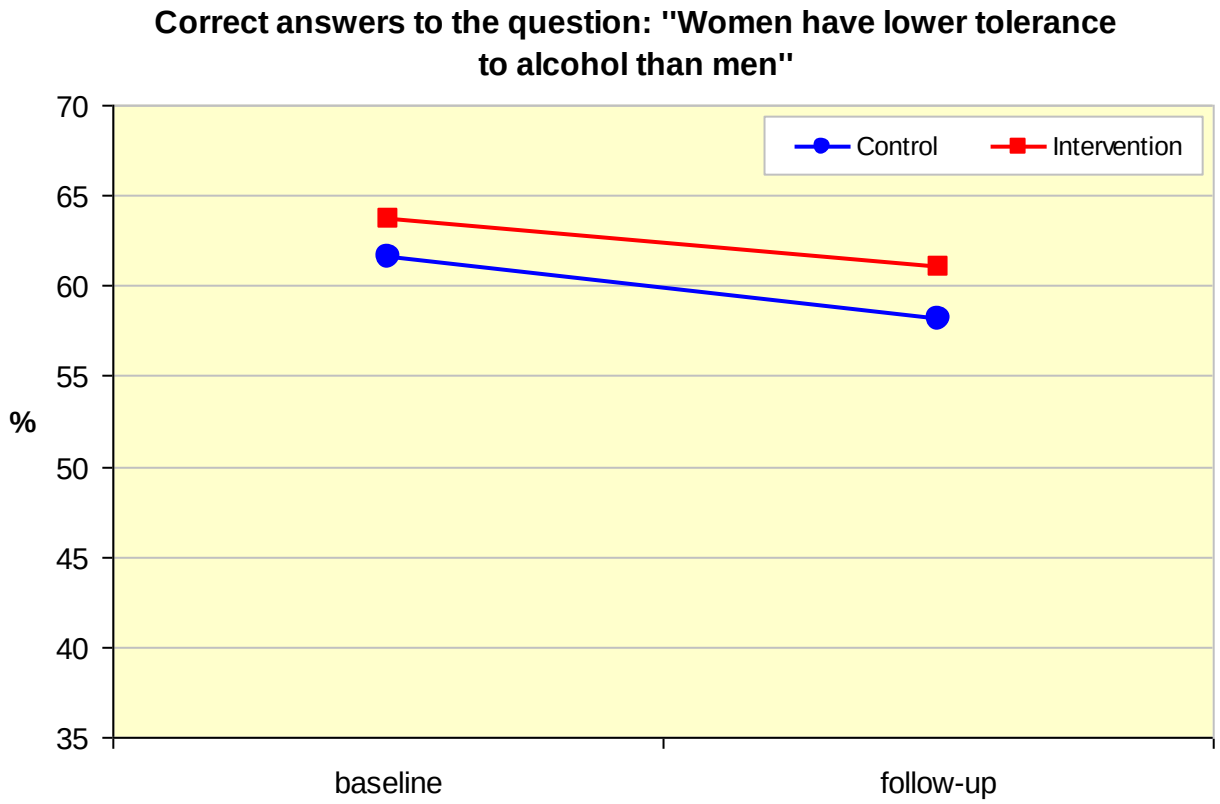

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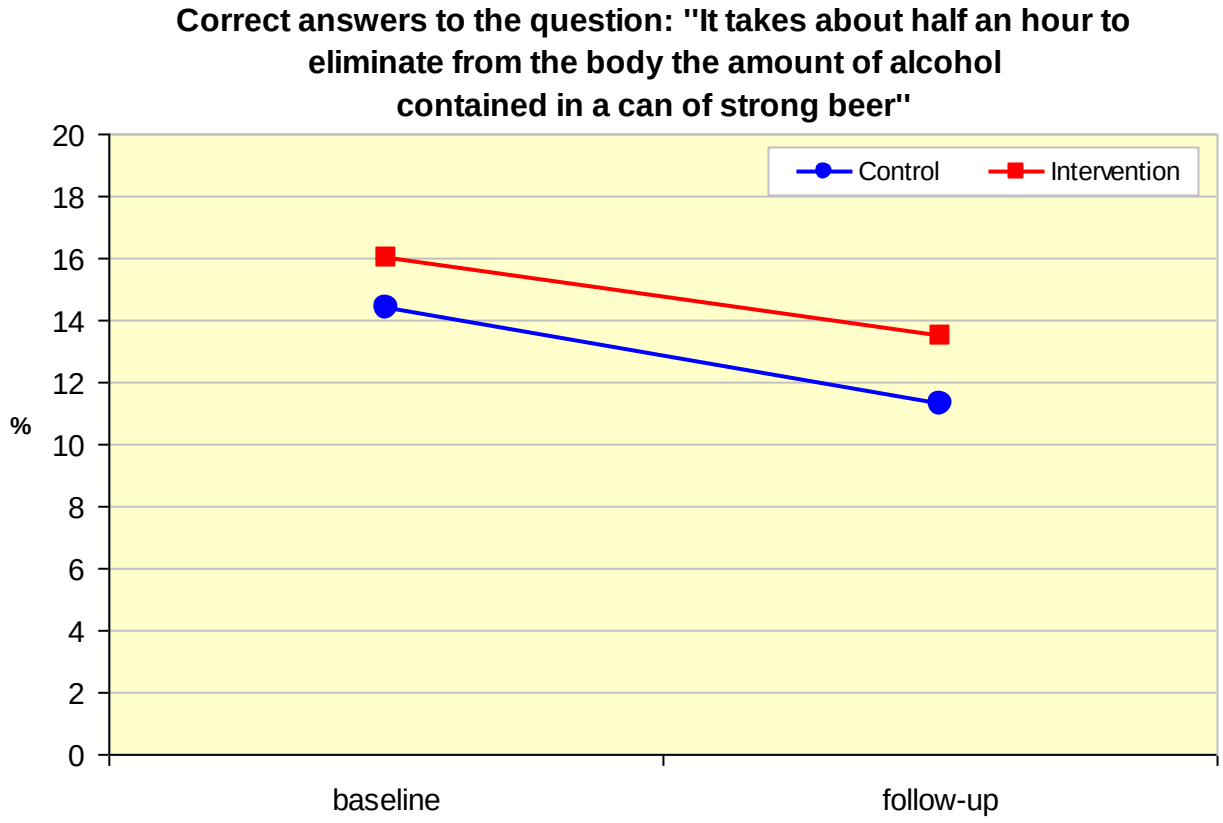

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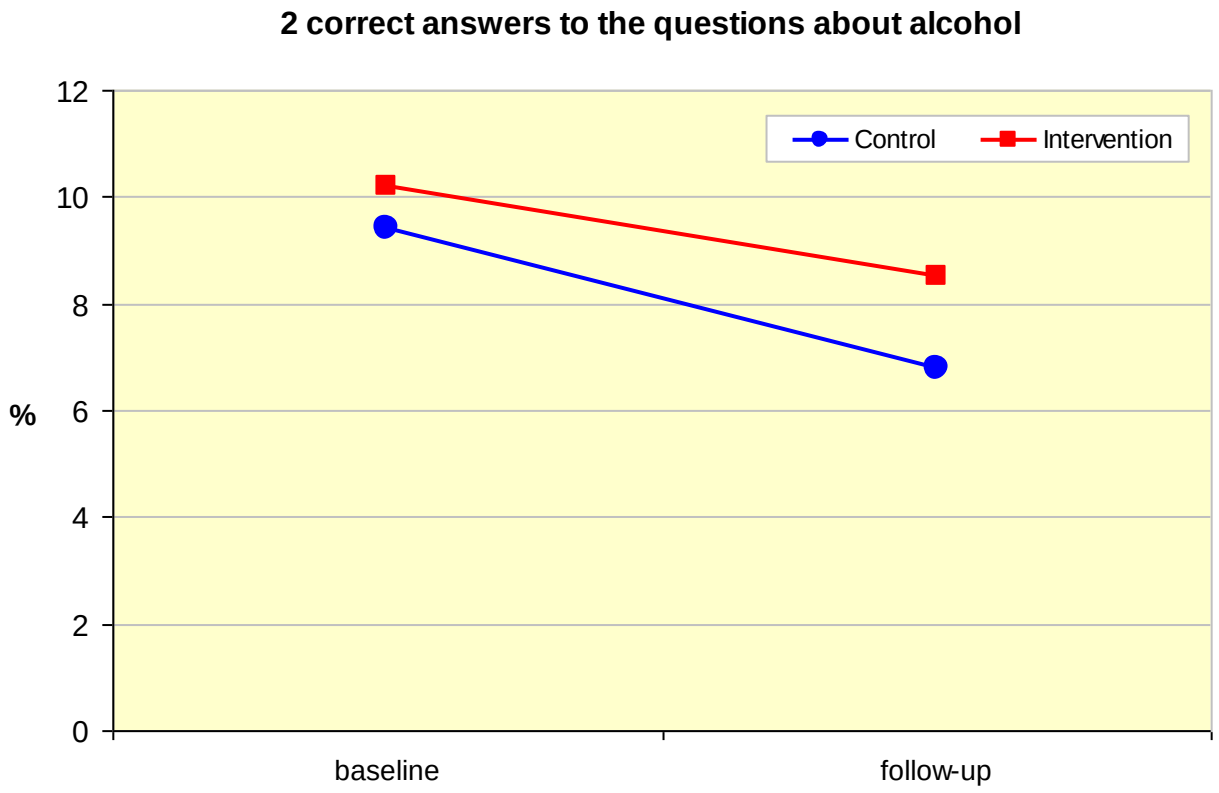

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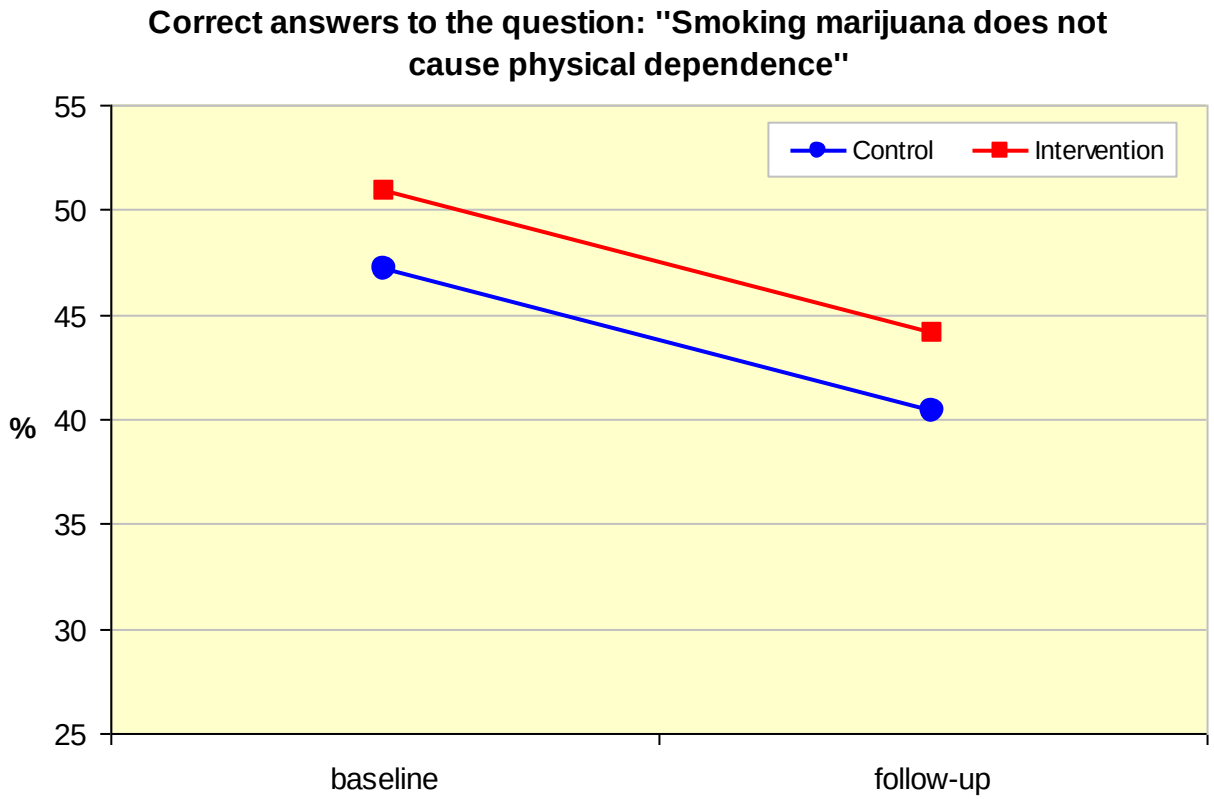

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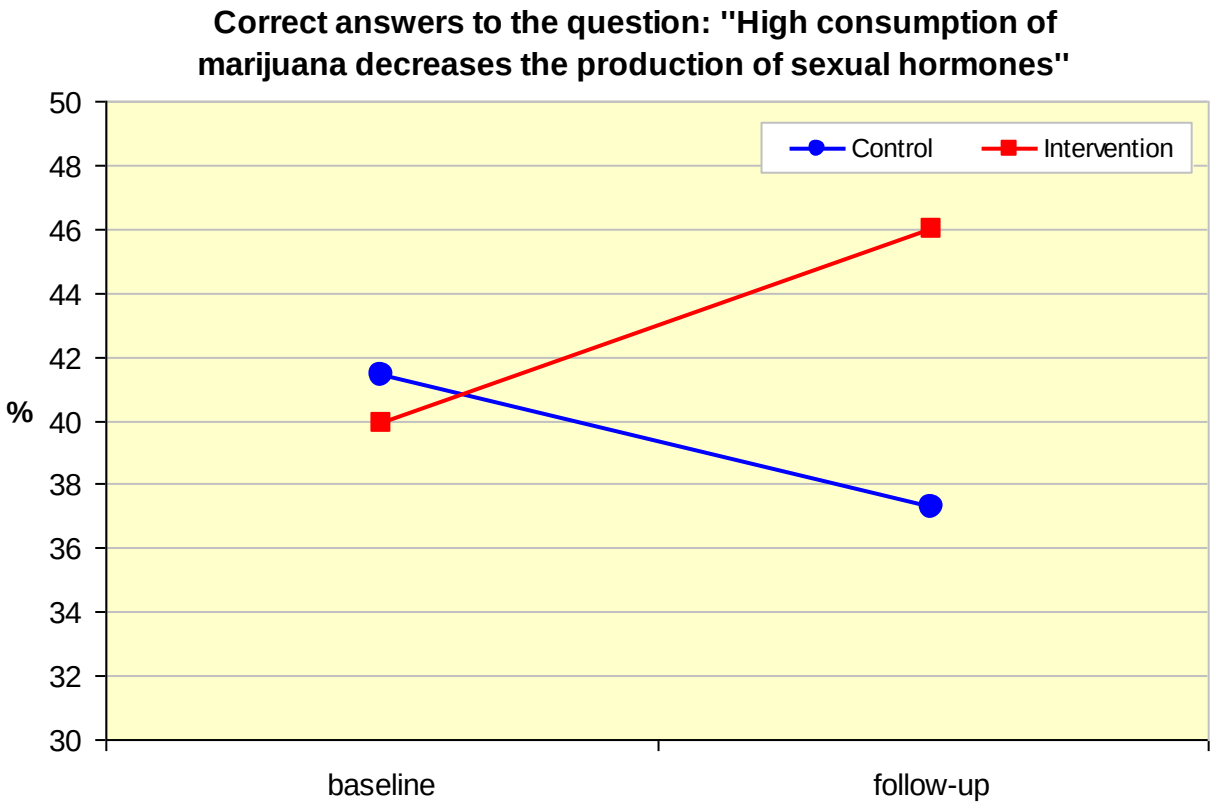

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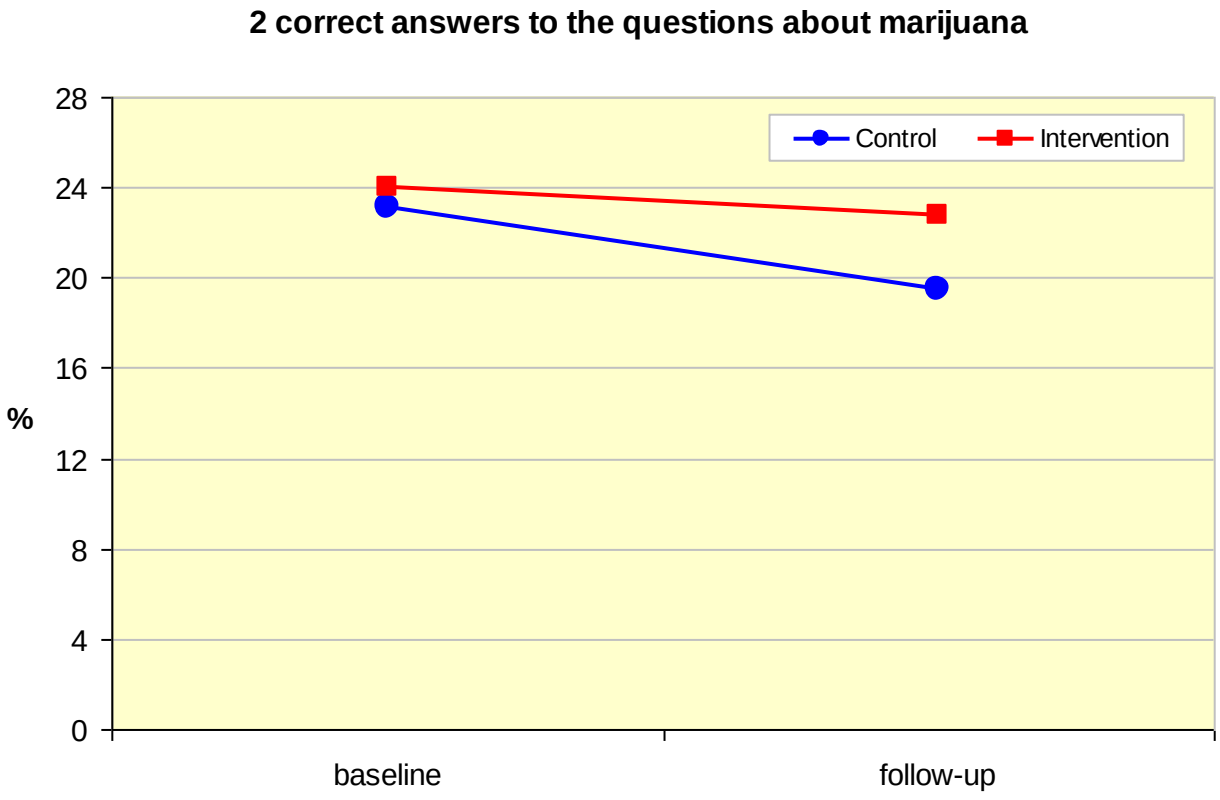

4.3. Logistic regression analyses: crude effectiveness results

Univariate logistic regression run on the overall follow-up matched sample showed **a slightly significant effect of the program on last 30 days advanced use of cigarette (regular and daily) and a statistically significant effect of the program on last 30 days advanced (regular and daily) use of alcohol** (Table 14).
No effect of the program is detected on drunkenness episodes, marijuana and other illicit drugs use.

Statistically significant effects are observed in favour of intervention pupils for **knowledge on alcohol and marijuana**, **negative beliefs on tobacco and alcohol**, and reduction of the **perception of use of tobacco, alcohol, marijuana and drunkenness episodes among peers**, and for the **improvement of class climate** (Table 15).
No effect of the program was detected on the perception of substance use among friends.

All these effects need to be studied in stratified and adjusted analysis, controlling for confounding factors and for cluster effect.

Table 14. Unadjusted Odds Ratios of behaviours, knowledge, beliefs, perception of use among peers and friends, and class climate at follow-up, intervention vs control pupils, matched sample

Oucomes	Crude OR	95% CI	P value
Behaviours			
Cigarettes use			
Last 30 days ALO	0.83	0.56-1.22	0.338
Last 30 days Regular	0.55	0.29-1.06	0.074
Last 30 days Daily	0.49	0.22-1.10	0.084
Alcohol drinking			
Last 30 days ALO	0.90	0.76-1.06	0.204
Last 30 days Regular	0.77	0.62-0.98	0.030
Last 30 days Daily	0.64	0.42-0.97	0.034
Drunkenness episodes			
Last 30 days ALO	1.07	0.76-1.50	0.702
Last 30 days Regular	1.11	0.69-1.77	0.670
Marijuana use			
Last 30 days ALO	0.82	0.53-1.26	0.363
Last 30 days Regular	0.74	0.43-1.28	0.287
Other drugs use			
Last 30 days ALO	1.06	0.76-1.46	0.735
Last 30 days Regular	1.12	0.72-1.77	0.617
Knowledge			
Nicotine is the substance in cigarettes that causes lung cancer			
No (correct) vs Yes/Don't know	0.87	0.62-1.21	0.399
One needs to smoke several cigarettes/day to become addicted			
No (correct) vs Yes/Don't know	1.04	0.90-1.19	0.610
Correct answers on tobacco			
1/2 correct answers vs 0	1.02	0.88-1.17	0.817
Women have lower tolerance to alcohol than men			
Yes (correct) vs No/Don't know	1.12	0.97-1.29	0.116
It takes about 30 minutes to eliminate from the body the alcohol contained in a can of strong beer			
No (correct) vs Yes/Don't know	1.23	0.99-1.51	0.057
Correct answers on alcohol			
1/2 correct answers vs 0	1.15	1.00-1.33	0.053
Smoking marijuana does not cause physical dependence			
No (correct) vs Yes/Don't know	1.16	1.01-1.34	0.038
High consumption of marijuana decreases sexual hormones			
Yes (correct) vs No/Don't know	1.43	1.24-1.65	0.000
Correct answers on marijuana and drugs			
1/2 correct answers vs 0	1.45	1.25-1.67	0.000
Beliefs			
Negative beliefs on tobacco			
High vs Middle/Low	1.18	1.02-1.35	0.022
Negative beliefs on alcohol			
High vs Middle/Low	1.23	1.07-1.41	0.003
Negative beliefs on marijuana and drugs			
High vs Middle/Low	1.12	0.97-1.29	0.127
Class climate			
Good vs Medium/Bad	1.31	1.10-1.56	0.002
Peers' prevalence			
none/less than half/about half smoke cigarettes	1.37	1.18-1.59	0.000
none/less than half/about half drink alcohol	1.27	1.10-1.47	0.001
none/less than half/about half get drunk	1.29	1.11-1.49	0.001
none/less than half/about half use marijuana or other drugs	1.19	1.03-1.37	0.021
Friends' prevalence			
none/less than half/about half smoke cigarettes	1.00	0.85-1.19	0.962
none/less than half/about half drink alcohol	1.06	0.90-1.25	0.457
none/less than half/about half get drunk	1.07	0.90-1.26	0.441
none/less than half/about half use marijuana or other drugs	1.04	0.88-1.23	0.659

*vs more than half/all of them/don't know

4.4. Logistic regression analyses: younger and older pupils

The stratification of effectiveness results by age shows **different effects of the program in the younger and older pupils** (Table 15); this will be taken into account in the adjusted analysis.
No differences among age groups emerged in cigarette, drunkenness, and other drugs behaviours.
On the contrary, **a statistically significant effect of the program on the reduction (24%) of alcohol drinking at least once in the last 30 days emerged among 10-14 years old pupils, together with a large reduction (32%) of regular alcohol drinking (more than 6 times in the last month).** Again, **in the younger age group, a large but only slightly significant effect (76% reduction, p=0.062) of the program was detected on marijuana use**.
No differences among age groups emerged in the indicators of tobacco and alcohol knowledge outcomes, and again **the effect on marijuana knowledge was stronger among 10-14 years old pupils**.

The effect on negative beliefs was stronger among the older pupils but the effect **on class climate and on the reduction of the perception of peers' prevalence was stronger among 10-14 years old pupils**. Among the latter, also a statistically significant reduction of the **perception of friends' tobacco and alcohol use was shown**.

From these data, there is some indication that the program was more effective among younger pupils reducing alcohol use, the perception of peers' and friends' cigarettes and alcohol use, improving knowledge on marijuana and improving class climate.

Table 15. Unadjusted Odds Ratios of behaviours, knowledge, beliefs, perception of use among peers and friends, and class climate at follow-up, intervention vs control pupils, matched sample, by age

Oucomes	10-14 years old (N=1493)			15-20 years old (N=1811)		
	Crude OR	95% CI	P value	Crude OR	95% CI	P value
Behaviours						
Cigarettes use						
Last 30 days ALO	0.73	0.28-1.93	0.523	0.83	0.54-1.27	0.390
Last 30 days Regular	0.53	0.11-2.62	0.433	0.55	0.27-1.11	0.095
Last 30 days Daily	0.53	0.05-5.08	0.580	0.47	0.20-1.12	0.089
Alcohol drinking						
Last 30 days ALO	0.76	0.58-0.99	0.042	1.02	0.81-1.27	0.873
Last 30 days Regular	0.58	0.39-0.86	0.006	0.93	0.70-1.25	0.628
Last 30 days Daily	0.74	0.35-1.59	0.446	0.60	0.36-0.98	0.043
Drunkenness episodes						
Last 30 days ALO	1.49	0.69-3.18	0.309	0.95	0.64-1.39	0.779
Last 30 days Regular	1.59	0.51-4.97	0.422	0.97	0.57-1.63	0.896
Marijuana use						
Last 30 days ALO	0.24	0.54-1.07	0.062	0.96	0.60-1.53	0.858
Last 30 days Regular	0.53	0.11-2.62	0.435	0.76	0.42-1.37	0.360
Other drugs use						
Last 30 days ALO	1.10	0.60-2.02	0.765	1.04	0.71-1.54	0.821
Last 30 days Regular	1.59	0.55-4.55	0.389	1.02	0.61-1.70	0.933
Knowledge						
Nicotine is the substance in cigarettes that causes lung cancer						
No (correct) vs Yes/Don't know	0.92	0.51-1.66	0.780	0.85	0.57-1.28	0.447
One needs to smoke several cigarettes/day to become addicted						
No (correct) vs Yes/Don't know	1.11	0.90-1.37	0.343	1.00	0.83-1.22	0.951
Correct answers on tobacco						
1/2 correct answers vs 0	1.08	0.88-1.34	0.450	0.99	0.82-1.19	0.899
Women have lower tolerance to alcohol than men						
Yes (correct) vs No/Don't know	1.17	0.94-1.45	0.160	1.08	0.89-1.31	0.424
It takes about 30 minutes to eliminate from the body the alcohol contained in a can of strong beer						
No (correct) vs Yes/Don't know	1.21	0.87-1.70	0.258	1.24	0.95-1.63	0.118
Correct answers on alcohol						
1/2 correct answers vs 0	1.16	0.93-1.44	0.176	1.13	0.93-1.37	0.236
Smoking marijuana does not cause physical dependence						
No (correct) vs Yes/Don't know	1.14	0.92-1.41	0.231	1.17	0.96-1.41	0.112
High consumption of marijuana decreases sexual hormones						
Yes (correct) vs No/Don't know	1.68	1.35-2.07	0.000	1.27	1.05-1.54	0.012
Correct answers on marijuana and drugs						
1/2 correct answers vs 0	1.51	1.22-1.88	0.000	1.39	1.14-1.69	0.001
Beliefs						
Negative beliefs on tobacco						
High vs Middle/Low	1.08	0.87-1.34	0.463	1.29	1.07-1.56	0.009
Negative beliefs on alcohol						
High vs Middle/Low	1.26	1.02-1.56	0.031	1.26	1.04-1.52	0.020
Negative beliefs on marijuana and drugs						
High vs Middle/Low	1.00	0.79-1.25	0.979	1.26	1.04-1.52	0.018
Class climate						
Good vs Medium/Bad	1.42	1.10-1.83	0.007	1.23	0.97-1.57	0.086
Peers' prevalence						
none/less than half/about half smoke cigarettes	1.57	1.24-1.97	0.000	1.27	1.04-1.55	0.018
none/less than half/about half drink alcohol	1.41	1.13-1.76	0.002	1.22	1.01-1.49	0.044
none/less than half/about half get drunk	1.34	1.07-1.68	0.010	1.26	1.03-1.54	0.027
none/less than half/about half use marijuana or drugs	1.16	0.93-1.45	0.185	1.21	0.99-1.47	0.060
Friends' prevalence						
none/less than half/about half smoke cigarettes	1.39	1.05-1.84	0.023	0.83	0.67-1.04	0.103
none/less than half/about half drink alcohol	1.38	1.07-1.80	0.014	0.89	0.72-1.10	0.293
none/less than half/about half get drunk	1.18	0.91-1.55	0.215	1.01	0.82-1.26	0.907
none/less than half/about half use marijuana or drugs	1.19	0.91-1.57	0.209	0.95	0.76-1.81	0.630

4.5. Multilevel adjusted regression analysis: adjusted effects of the program

In order to take into account the hierarchical level of the data, multilevel adjusted models were used to estimate the adjusted effect of the program on the main outcomes (use of substances, beliefs, perception of peers' prevalence, class climate). Zone was set up as I hierarchical level (random effects). It was not possible to add school or class levels because the model so built did not converge.

Since at baseline large differences were shown in prevalence of use among zones, indicators of last 30 days zone prevalence of each substance was derived from the baseline database (n=4078). Age, the baseline level of the indicator, and the baseline prevalence of tobacco, alcohol and marijuana use in the last 30 days were added as confounding variables in the model. With this strategy, the effect so estimated is adjusted for confounding factors.

The same model was run on the 10-14 years old subgroup: in this case, age was not added to the model.

The effect of the program on the substance use outcomes (cigarettes, alcohol and marijuana) was consistent across substances, showing for all of them a protective effect of the program (Table 16).

However, the effect in reducing any use of cigarettes (at least once in the last 30 days indicator) was not statistically significant (reduction of 17%, p=0.357 n.s.). **The effect in reducing regular cigarette use (at least 6 times in the last 30 days) was large but only slightly significant (reduction of 47%, p=0.065), as well as the effect in reducing daily cigarette use (at least 20 times in the last 30 days) (reduction of 55%, p=0.064).** Formally these effects were not statistically significant, so we can't exclude they are due to chance. However, since cigarette use was very infrequent in our sample, the lack of significance **could be due to the low sample size**, that was insufficient to reach statistically significant effects for a rare outcome. When limiting the analysis at the 10-14 years old pupils sample, the effect is apparently larger, but again not statistically significant.

The same reasoning must be applied to the effect of the program on marijuana use: again, the effect in reducing any marijuana use (at least once in the last 30 days) and regular marijuana use (at least 3 times in the last 30 days) was not statistically significant. However, **a large statistically significant effect was detected in the reduction of any marijuana use among the younger pupils (reduction of 83%, p=0.037).**

On the contrary, a statistically significant effect of the program was detected on all alcohol use indicators: the program reduced any alcohol use (at least once in the last 30 days) of 19% (p=0.025), regular alcohol use (at least 6 times in the last 30 days) of 27% (p=0.010) and daily alcohol use (at least 20 times in the last 30 days) of 38% (p=0.030). Moreover, the

effect was stronger among 10-14 years old pupils: among them, the reduction was of 30% for any alcohol use (p=0.015), and of 42% for regular alcohol use (p=0.008).

The analysis of possible mediators of effect showed an improvement of **negative beliefs** that was statistically significant in case of **negative beliefs towards cigarettes (+19%, p=0.031) and alcohol (+28%, p=0.002) and was only slightly significant in case of marijuana (+16%, p=0.076)**.

The improvement of class climate was significantly in favour of intervention pupils (+36%, p=0.001) and it was bigger among 10-14 years old ones (+53%, p=0.002).

Finally, the program reduced the erroneous perception of peers' prevalence of cigarettes and alcohol use (p<0.0001 in both cases) and again this effect was stronger among younger pupils. The reduction of perception of peers' prevalence of drunkenness episodes and marijuana use did not reach statistically significance. **Among the younger pupils, also the perception of friends' prevalence of cigarettes and alcohol use was statistically significant, in favour of intervention pupils (p=0.017 and p=0.022 respectively).**

4.6. Conclusions

In conclusion, the adjusted analyses taking into account baseline level of the indicator, cluster effect at zone level, age and zone's prevalence of cigarette, alcohol and marijuana use showed that the Unplugged program was effective in:

- **(reducing recent regular and daily cigarettes use – only slightly significant);**
- **reducing recent alcohol use, regular and daily alcohol use, with a stronger effect among younger pupils;**
- **reducing recent marijuana use among younger pupils;**
- **improving class climate;**
- **improving negative beliefs on cigarettes and alcohol (and probably marijuana – only slightly significant);**
- **reducing the erroneous perception of peers' prevalence of cigarettes and alcohol use, with a stronger effect among younger pupils;**
- **reducing the erroneous perception of friends' prevalence of cigarettes and alcohol use among younger pupils.**

From these results, we can conclude that Unplugged reached in Nigeria good results in preventing cigarettes, alcohol and marijuana use, with effects on class climate and normative beliefs, similarly to what observed in the EUDap original effectiveness study. Therefore, the implementation of Unplugged at a larger level in the country can be supported, with the attention of focusing on younger adolescents (less than 14 years old).

Table 16. Multilevel adjusted Odds Ratios of behaviours, knowledge, beliefs, perception of use among peers and friends, and class climate at follow-up, intervention vs control pupils, matched sample, overall sample and 10-14 years old subgroup

Oucomes	Overall sample*			10-14 years old**		
	adj OR	95% CI	P value	adj OR	95% CI	P value
Behaviours						
Cigarettes use						
Last 30 days ALO	0.83	0.55-1.24	0.357	0.57	0.20-1.64	0.294
Last 30 days Regular	**0.53**	**0.27-1.04**	**0.065**	0.24	0.03-2.02	0.188
Last 30 days Daily	**0.45**	**0.19-1.05**	**0.064**	-	-	-
Alcohol drinking						
Last 30 days ALO	**0.81**	**0.68-0.98**	**0.025**	**0.70**	**0.53-0.93**	**0.015**
Last 30 days Regular	**0.73**	**0.57-0.93**	**0.010**	**0.58**	**0.39-0.87**	**0.008**
Last 30 days Daily	**0.62**	**0.40-0.96**	**0.030**	0.91	0.41-1.99	0.804
Marijuana use						
Last 30 days ALO	0.80	0.51-1.27	0.349	**0.17**	**0.03-0.90**	**0.037**
Last 30 days Regular	0.81	0.45-1.43	0.459	0.59	0.11-3.12	0.534
Beliefs						
Negative beliefs on tobacco						
High vs Middle/Low	**1.19**	**1.02-1.39**	**0.031**	1.13	0.89-1.42	0.329
Negative beliefs on alcohol						
High vs Middle/Low	**1.28**	**1.09-1.50**	**0.002**	**1.26**	**0.99-1.59**	**0.058**
Negative beliefs on marijuana and drugs						
High vs Middle/Low	**1.16**	**0.98-1.38**	**0.076**	1.04	0.80-1.33	0.790
Class climate						
Good vs Medium/Bad	**1.36**	**1.13-1.63**	**0.001**	**1.53**	**1.16-2.01**	**0.002**
Peers' prevalence						
none/less than half/about half smoke cigarettes	**1.39**	**1.19-1.62**	**0.000**	**1.60**	**1.26-2.03**	**0.000**
none/less than half/about half drink alcohol	**1.34**	**1.15-1.56**	**0.000**	**1.42**	**1.13-1.79**	**0.003**
none/less than half/about half get drunk	1.07	0.96-1.31	0.443	1.15	0.88-1.51	0.309
none/less than half/about half use marijuana or drugs	1.03	0.86-1.23	0.770	1.22	0.92-1.63	0.167
Friends' prevalence						
none/less than half/about half smoke cigarettes	1.00	0.83-1.19	0.968	**1.43**	**1.07-1.93**	**0.017**
none/less than half/about half drink alcohol	1.07	0.91-1.27	0.419	**1.38**	**1.05-1.81**	**0.022**
none/less than half/about half get drunk	1.08	0.91-1.29	0.375	1.21	0.92-1.61	0.176
none/less than half/about half use marijuana or drugs	1.03	0.86-1.23	0.770	1.22	0.92-1.63	0.167

* multilevel model with zone as first level, and baseline level of the indicator, age and zone's baseline prevalence of tobacco, alcohol or marijuana use specific for the indicator, as confounding factors

* multilevel model with zone as first level, and baseline level of the indicator and zone's baseline prevalence of tobacco, alcohol or marijuana use specific for the indicator, as confounding factors