

“GiochiAMO”: a school-based smoking and alcohol prevention program for children – a pilot randomized field trial. Part 2

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Parole chiave: Prevenzione, scuola, fumo, giovani, alcol, giochi da tavolo, carte

Abstract

Background. Young people who begin to smoke at an early age are at a higher risk of becoming occasional or regular smokers and establishing a premature dependence. It is fundamental to act as soon as possible, from very early childhood, to prevent harmful behaviors for health such as smoking and drinking alcohol. Young people must be encouraged to adopt healthy lifestyles.

Objectives. The aim of the study is two-fold. First, increasing the knowledge about the negative health effects of cigarette smoking and alcohol consumption among children aged 9-10 years; and second, to introduce and reinforce life skills in order to learn how to tackle social influences that encourage children to smoke and to drink alcohol.

Methods. A pilot randomized field trial was conducted in May-June 2017. Four primary school classes in Rome were randomized to either the intervention or the control group. Both groups participated in an oral presentation about the risks and consequences of smoking and alcohol consumption, and the concept of life skills. The intervention group participated in two gaming sessions, each lasting 1.5 hours. Children were involved in six games aiming to deliver and reinforce knowledge about the target themes of the study. A 21 multi-response questions questionnaire was handed out to both groups at the beginning and at the end of the study. Eleven questions were about smoking; five questions about alcohol; five questions about life skills. Each question item included one correct answer. For each domain, a score was computed (total; smoking; alcohol; life skills).

Results. 67 children participated in the study (34 in the intervention and 33 in the control group). Univariate analyses showed significant differences among the intervention group before and after the intervention for total score ($p<0.001$), smoke score ($p<0.001$), and life skills score ($p=0.003$). No significant differences among the intervention group before and after the intervention were reported for alcohol score ($p=0.076$). Regarding the control group univariate analysis showed significant differences in total score ($p=0.001$) and life skills score ($p=0.005$). Multivariate analysis revealed that enrollment in the intervention was the only variable that had a significant positive influence on smoking knowledge score ($\beta=1.070$, $p=0.05$).

Conclusions. This pilot study shows that the intervention was effective among the intervention group for all the scores: total score, smoke score and life skills score, but ineffective for alcohol. Overall, the combination of a presentation and games was effective in increasing life skills knowledge.

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Introduction

The health of the European youth population is a critical and important aspect for Europe's sustainability and prosperity. A healthy population may result in substantial benefits in terms of public health, productivity and social development (1). Most of the health problems - such as cardiovascular diseases, diabetes, stroke and cancer have their genesis in the child and adolescent years (2). Therefore, it is of immense importance to encourage children to adopt healthy lifestyles.

With a smoking rate of 20%, among people aged 15 years, Italy is far above the European average (14%) (3). Besides, it is not only smoking that poses an important threat to the health of Italian adolescent, but also alcohol consumption. The Health Behavior in School-aged Children (HBSC) survey of 2013-2014 revealed that 3% of the Italian girls and 7% of Italian boys aged eleven drink at least once a week, while the prevalence in thirteen year old children is 8 % for girls and 13% for boys (4). This shows an urgent need for improvement.

There are various theories about why young people start smoking and drinking. The school environment, in particular, can play a crucial role in determining the behavior of children. Adolescents generally spend a great amount of time at school. Therefore, this setting seems to be an ideal place for smoking and alcohol use prevention. School-based prevention programs can have several short- and long-term benefits. Among others, these include improved student health, an increased social awareness about the links between alcohol consumption, cigarette smoking and health, and finally, in the long-term, reduced healthcare costs. La Torre et al (2005) (5) systematically reviewed that smoking prevention programs are effective and demonstrated a decreased prevalence

of smoking among students exposed to social influence programs compared to students in control groups. One of the major success factors of a prevention program is the active participation of students with a peer-education approach, (6) social reinforcement (7) and an active involvement of teachers. Therefore, interventions that integrate the doctrinal approach with both social and behavioral aspects may have an exponential effect on effectiveness (8). Considering that substance use in elementary school is rare and the beliefs about the effects of substances are primarily negative, according to Onrust (9), substance use prevention, in this developmental stage, should not necessarily address the risks of the substance, but should focus on teaching children basic skills in order to help them in mastering their primary developmental challenges.

Overall, 'GiochiAMO' ('Let's play') is a newly developed intervention that includes class-based educational lessons and gaming sessions. GiochiAMO is structured in two sections: 'Mangiamo', that focuses on physical activity and healthy diets (described in detail elsewhere) and 'Sfumiamo', that focuses on smoking and alcohol consumption through strengthening general life skills. The present study focuses exclusively on 'Sfumiamo'. Therefore, the aim of this study was to examine whether 'Sfumiamo' during a pilot project was effective for participating children and whether knowledge about health risk increased.


Objective of 'Sfumiamo'

The aim of the 'Sfumiamo' is twofold: firstly, to increase the knowledge about the negative health effects of cigarette smoking and alcohol consumption by the use of table games and cards among children aged 9-10 years; secondly, to introduce and stress the concept of 'life skills', in order to teach how to tackle social influences of smoking and drinking.

Materials and Methods

The prevention program ‘Sfumiamo’ was tested with a two-arm pilot cluster randomized-controlled trial. The pilot study took place in Rome, Italy, in May-June 2017. ‘GiochiAMO’ is a school-based primary prevention program for students in grade 4, aged 9-10 years and was designed by the Department of Public Health and Infectious Diseases of La Sapienza, University of Rome, Italy.

Participants

In May-June 2017, eligible 4th grade students (present at the enrolment ) at the “Fratelli Bandiera” school in Rome were invited to participate in the study. Informed consent letters with details about the study purpose, its importance, eligibility of participants and ethical issues, were given to the parents of the students and their teachers.


The intervention

The intervention comprises an oral presentation and board and card games developed by the authors. Children in the control group only took part/received the oral presentation. The 45-minute oral presentation focused on risks and consequences of smoking and drinking alcohol, and introduced the topic of life skills. Children in the intervention group were invited to participate in two gaming activities, each lasting 1.5 hours. The gaming activity included six games, all designed and monitored by the research group. Thirty playing cards and one board game were designed. The games stressed the consequences of smoking and alcohol consumption on four domains: health, monetary, society and healthy citizen. Furthermore, the team designed three roleplays to make children experience in first person social pressure and let them react to it: the researchers provided models

of solution and invited the children to create new ones to be shared with others.

Survey/Questionnaire

To evaluate differences between the intervention group and the control group, a questionnaire consisting of 21 multi response questions (11 questions concerning cigarette smoke, 5 questions concerning alcohol, 5 questions concerning life skills) was designed. Each item had one correct answer. A further question was administered in the questionnaire, focusing on the personal attitude of the child towards these themes with the aim of enabling an elaborate and descriptive analysis about their perception of these topics. One part of the questionnaire focused on the demographics (sex and age) and the smoking status of children’s parents (both parents smoke, one parent smokes, neither smoke).

The questionnaire was administered to both control and intervention groups, at the beginning and at the end of the study. Pre--post-intervention answers of everyone were paired by assigning an alphanumeric code to each questionnaire. Each correct answer was evaluated with one point. Wrong answers or unanswered questions were evaluated with zero points. To perform the statistical analysis, four scores were created:

- The global score (ScTot) derived from the sum of correct answers given to smoke and alcohol issues and life skills questions;
- The smoke score (ScSmoke) derived from the sum of correct answers given to smoke questions;
- The alcohol score (ScAlcohol) derived from the sum of correct answers given to alcohol questions;
- The life skills score (ScLifeskills) derived from the sum of correct answers given to life skills questions.

Each score was itemized with T0, if referred to baseline results and T1, if referred to post- intervention results. In addition, a Delta Score for each score was derived

from the differences between T1 scores and the related T0 scores (i.e. DeltaScSmoke derived by ScSmoke T1 minus ScSmoke T0) was created.

Statistical analysis

The statistical data were analyzed using the software SPSS (Statistical Package for Social Sciences) version 24. To evaluate differences between the intervention and the control groups, a univariate analysis of Delta Scores using Mann Whitney test was performed. A univariate analysis using Wilcoxon test was applied to evaluate differences among the groups before and after the intervention. A multivariate analysis was conducted with backward-stepwise elimination procedure of non-significant variables generating a minimal model. The following variables were included in the linear regression model: gender, age, intervention, parents smoking status. The level of significance was set at $p < 0.05$.

Sample Size

Sample size calculations were made using the software Epicalc 2000. For this calculation, we used the Global score (min=0; max=21) hypothesizing:

- Average score pre-intervention = 10 points
- Average score post-intervention = 13 points (increasing of the score by 30%)
- Standard Deviation = 2
- Significance Level = 0.05
- Power = 80%

Sample size calculations resulted in 12 units for both the intervention and the control groups. Taking into account the cluster design, an increase of 20% was applied. So for each group we had to recruit at least 15 pupils.

Ethical statement

The study has been conducted according to the principles expressed in the Declaration of Helsinki. Before students could take part

in the study, parents were asked to sign an informed consent form concerning the processing of data (see annex for informed consent). The school and parents were fully informed about the study purpose. Anonymity has been guaranteed at all times. The Local Ethical Committee approved the study.

Results

In total 67 children participated in this study. Two classes (n=18 children and n=16 children) were randomized to the intervention (lecture, games and the post-intervention questionnaire) and two classes (n=14 children and n=19 children) were randomized to the control group (Figure 1).

The mean age of the participants was 9,4 years. Males and females were distributed equally within the intervention and control classes, but overall more males than females participated. In both groups, around 65% of parents were non-smokers (Table 1).

If needed, children received assistance for filling in the questionnaires; hence, the main reason for missing data and no full completion of the questionnaire was lack of knowledge about the answers. Children who did not fill out both questionnaires (pre- and/or post) or did not attend the oral presentation were excluded from the study. One child of the intervention group was lost at follow-up since he did not complete the post-intervention questionnaire. No child was lost at follow-up in the control group.

Primary outcomes were smoking, alcohol and life skills knowledge score and total score. The scores are reported in Table 2 and Table 3. Secondary outcomes were delta score, calculated as “post intervention-pre-intervention”, and are shown in Table 4. All the analysis have been based on the differences observed for each child.

As shown in Table 2, the univariate analysis, using Wilcoxon test, showed

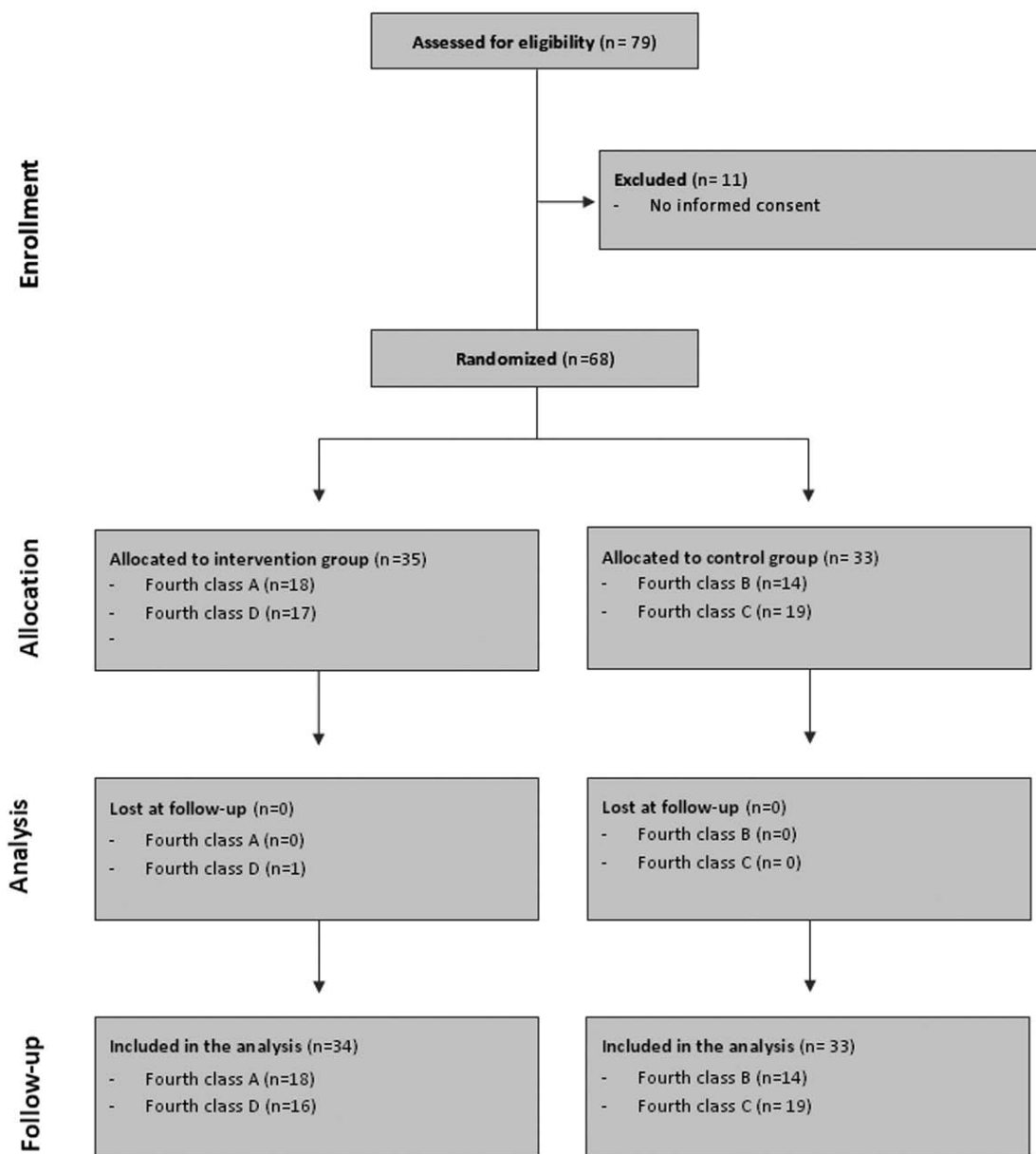


Figure 1. Flow of Participants through the Study

Table 1 - Descriptive characteristics of the sample

| | | Intervention | Control | Tot |
|------------------------|-----------------------|--------------|------------|-----|
| Students enrolled | | 34 | 33 | 67 |
| Class A | | 18 | | |
| Class D | | 16 | | |
| Class B | | | 14 | |
| Class C | | | 19 | |
| Gender | Male | 22 (64.7%) | 21(63.6%) | 43 |
| | Female | 12 (35.3%) | 12 (36.4%) | 24 |
| Parents smoking status | Yes (At least one) | 11 (32.4%) | 12 (36.4%) | 23 |
| | No | 23(67.6%) | 21 (63.6%) | 44 |
| Age (mean) | | 9.2 | 9.6 | 9.4 |

significant differences among the intervention group before and after the intervention concerning the *total score* ((ScTotT0, ScTotT1 ($p<0.001$)), the *smoke score* ((ScSmokeT0, ScSmokeT1 ($p<0.001$)), and the *life skills score* ((ScLifeskillsT0, ScLifeskillsT1 ($p<0.003$)). Within the intervention group, no significant differences between the ScAlcoholT0 and ScAlcoholT1 were reported ($p=0.076$). Within the control group, a significant difference was revealed for the *life skills*

score ($p<0.005$). This suggests that the oral presentation improved knowledge concerning life skills, but not smoking and alcohol-related knowledge.

The univariate analysis of delta score, conducted with Mann Whitney test, did not show significant differences between the intervention and the control groups for all scores. The results of the analysis are shown in Table 3.

Table 4 shows the results of univariate analyses using Mann-Whitney test and

Table 2 - Descriptive and Univariate analysis for scores within the groups

| SCORES | Intervention | | | Control | | |
|----------------|--------------|------------------|------------------|------------|------------------|--------------|
| | Mean (DS) | Median (Min-Max) | p* | Mean (DS) | Median (Min-Max) | p* |
| ScTotT0 | 11.2 (2.9) | 11 (4-16) | <0.001 | 10.5 (2.6) | 10 (6-17) | 0.001 |
| ScTotT1 | 13.63 (4.2) | 15 (1-19) | | 12.3 (3.8) | 12 (6-19) | |
| ScSmokeT0 | 6.14 (1.6) | 6 (2-10) | <0.001 | 6 (1.6) | 6 (3-10) | 0.175 |
| ScSmokeT1 | 7.51 (2.4) | 8 (1-11) | | 6.6 (2.4) | 7 (2-11) | |
| ScAlcoholT0 | 3.03 (1.0) | 3 (1-5) | 0.076 | 2.6 (1.4) | 3 (0-5) | 0.124 |
| ScAlcoholT1 | 3.4 (1.5) | 4 (0-5) | | 3.09 (1.5) | 3 (0-5) | |
| ScLifeskillsT0 | 2.03 (1.0) | 2 (0-4) | 0.003 | 1.84 (1.2) | 2 (0-5) | 0.005 |
| ScLifeskillsT1 | 2.71 (1.1) | 3 (0-5) | | 2.6 (0.9) | 3 (0-4) | |

*Wilcoxon p value

Table 3 - Descriptive and Univariate analysis for delta score

| | Intervention group VS control group | | | | p** |
|-------------------|-------------------------------------|--------------|------------------|--------------|-------|
| | MEAN (SD) | | MEDIAN (Min/Max) | | |
| | Control | Intervention | Control | Intervention | |
| DeltaScTot | 1.81 (2.8) | 2.43 (3.2) | 1 (-4/8) | 3 (-4/8) | 0.133 |
| DeltaScSmoke | 0.6 (2.3) | 1.37 (1.8) | 0 (-3/5) | 1 (-3/5) | 0.069 |
| DeltaScAlcohol | 0.42 (1.32) | 0.37 (1.5) | 1 (-2/4) | 0 (-2/4) | 0.974 |
| DeltaScLifeskills | 0.75 (1.3) | 0.4 (1.4) | 1 (-3/3) | 0,5 (-3/3) | 0.821 |

**Mann Whitney p value



Wilcoxon test and the multivariate analysis (Beta coefficients).

The univariate analysis, conducted with Mann Whitney test, comparing intervention and control group, showed significant increase in smoke score (ScSmokeT1, P§=0.048) (Table 4). Hence, the combination of presentation and game sessions appears to be effective in increasing the knowledge about smoke. No significant differences were found for alcohol score, life skills score and total score (Table 4).

Whereas, in each group, life skills score significantly increased among children (p=0.003; p=0.005), no efficacy was demonstrated for alcohol knowledge (p=0.076; p=0.124).

A multivariate analysis (Table 4) was conducted with stepwise with backward elimination of non-significant variable (p<0.05). The following variables were included in the linear regression model: gender, age, intervention, parents smoking status. The enrollment in the intervention is

Table 4 – Results of the univariate and multivariate (beta-coefficient) analysis

| Variables | Intervention Median (range) | Control Median (range) | P§ | Beta* | P^ |
|----------------|--------------------------------|---------------------------|--------------|-------|-------------|
| ScTotT0 | 10 (3-14) | 8 (5-14) | 0.054 | 0.718 | 0.160 |
| ScTotT1 | 12.5 (3-15) | 9 (4-16) | 0.084 | 1.479 | 0.082 |
| P^ | <0.001 | 0.041 | | | |
| ScSmokeT0 | 6 (2-10) | 6 (3-10) | 0.309 | 0.300 | 0.433 |
| ScSmokeT1 | 8 (2-11) | 7 (2-11) | 0.048 | 1.070 | 0.05 |
| P^ | < 0.001 | 0.175 | | | |
| ScAlcoholT0 | 3 (1-5) | 3 (0-5) | 0.259 | 0.392 | 0.180 |
| ScAlcoholT1 | 4 (0-5) | 3 (0-5) | 0.264 | 0.409 | 0.247 |
| P^ | 0.076 | 0.124 | | | |
| ScLifeskillsT0 | 2 (0-4) | 2 (0-5) | 0.360 | 0.262 | 0.332 |
| ScLifeskillsT1 | 3 (1-5) | 3 (0-4) | 0.533 | 0.209 | 0.342 |
| P^ | 0.003 | 0.005 | | | |

*beta-coefficient of the variable Intervention of the regression analysis, in which age, gender and smoking status of the parents, intervention were included; P^ indicates the Wilcoxon test; P§ indicates the Mann-Whitney test

the only variable that positively influences smoking knowledge score in a significant way ($\beta=1.070$, $p=0.05$).

Discussion

In the present study, a pilot randomized controlled field trial was conducted to examine the effects of 'GiochiAMO' on children's knowledge about the negative health effects of cigarette smoking and alcohol, as well as knowledge about life skills. Overall, the results of this pilot study are encouraging. The results showed that there were significant differences between the intervention group and the control group. Children's knowledge concerning the negative health effects of smoking significantly increased in the intervention group compared to the control group. Hence, the combination of an oral presentation and game based learning proves effective in increasing smoking related knowledge. The control group's life skill score also improved with solely the oral presentation.

Such effects on students' knowledge have also been found in a similar study (10). A game is an important tool for the delivery of information and reinforcement of knowledge in children (11, 12). Lakshman (12) developed a card game for the use in primary schools. The results of their cluster randomized controlled trial demonstrated that at follow-up, more children in the intervention schools stated they were 'currently eating a healthy diet' (39.6%) or 'would try to eat a healthy diet' (35.7%) than in control schools (34.4% and 31.7% respectively; Chi-square test $p < 0,001$). Already in 1960 Froebel, the pioneer in early childhood education and inventor of the Kindergarten, stressed the importance of games for a child's development (13).

Adolescence is a late period for effective interventions as young people are likely

to have already adopted certain habits. Therefore, it is fundamental to act as soon as possible, from very early childhood, to prevent harmful behaviors for health (14,15) and prevention programs for the use of these substances should preferably be implemented in elementary/primary school (16).

While 'GiochiAMO' proved to be effective for smoking related knowledge and life skills, it was ineffective for alcohol related knowledge. These results may be explained by several reasons: the actual benefits of setting up alcohol interventions in elementary school are still controversial, as children are not yet faced with alcohol and do not have great knowledge about this topic. To obtain long-term results, the normative education must be accompanied by life skills training and the development of practical activities (17). Learning life skills reinforces the acquisition of knowledge, positive attitudes and values in order to establish healthy and positive behaviors (18). Therefore, life skills can contribute to primary prevention and health protection, since they transform knowledge, attitudes and values into abilities and actions (19–23).

Strengths and Limitations

The main strength of this study is the very young age of the target population. According to literature, this kind of intervention has only been conducted among adolescents (24), but not children. In addition, most school-based programs have been developed for and delivered in middle schools but programs aimed at elementary schools, particularly grades 3 to 5 are less common (25). Furthermore, the intervention introduces the concept of life skills already in children. In 1994, the World Health Organization stated that psychosocial competences play an important role in promotion of health, in terms of physical, mental and social

well-being. In particular, where health problems are related to behavior, and where the behavior is related to an inability to effectively deal with pressures and stressors in life (26). ‘Sfumiamo’ targets life skills at a young age, and has a strong focus on building drug resistance skills, general self-regulation and social skills – factors that have been proven to be most effective in preventing substance abuse (27). Besides, another strength of the study is the positive response among students to the program, the games and the activities. It balances fun with seriousness. In addition, effective school-based interventions should be long term and easily sustainable. ‘GiochiAMO’ is an intervention that can easily fit in with the education curriculum and does not rely on continued input from health professionals.

Nevertheless, some limitations of the current study must be considered. A major limitation of our study was that the intervention has been tested only over a relatively short period. A longer-term assessment would be required to determine the program’s effectiveness/efficacy. Some authors, for instance, recommend a follow-up interval of at least 6 months after the intervention (28). Another limitation is that the study has been done on a small scale (only one school, small sample size); therefore, it is appropriate to note that the results cannot be generalized to other groups of students outside the group of respondents (no external generalizability). Since this intervention aims to increase the knowledge about smoking and alcohol, and to strengthen life skills, it would be also desirable to evaluate a change in attitudes and behaviors. In light of these considerations, it is necessary to extend the intervention to a larger sample, followed over a longer period, also considering any cultural and geographical differences that could affect a child’s educational process. A crucial point to achieve overall efficacy for interventions is to ensure a long-lasting

reinforcement approach, lasting even years, to obtain real improvements in attitude and behavior (24,29).

Conclusions

In conclusion, ‘Sfumiamo’ yielded positive and encouraging results when applied in schools. From the results, it can be stated that:

- Smoking related and life skills related knowledge increased;
- Students involved were positive about the content of the intervention offered and the teaching methods used.

Furthermore, this pilot study stressed the need for educating and teaching children about smoking and alcohol habits and the importance of intervening at a very early stage of their education. The intervention offers a strong and fundamental tool in life skills training to educate children how to fightback social pressure as well as to build a steady resilient personality to face life’s challenges. To our knowledge, no similar study has been conducted including such a young target population. However, to test for, and achieve long-term effectiveness, as well as evaluate attitude changes, further studies over a longer period and including a larger sample size are needed.

Note

Furthermore, the pilot study aimed to enhance children’s life skills including assertiveness, problem solving and self-esteem. In order to reduce the risk of up-taking smoking and drinking alcohol, it is fundamental to equip children with these tools that help him to fightback social pressure.

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Riassunto

“GiochiAMO”: un programma scolastico per la prevenzione di fumo ed alcol tra i bambini - un trial pilota randomizzato sul campo. Parte 2

Introduzione. Chi comincia a fumare da giovane ha un rischio maggiore di diventare fumatore occasionale o abituale, quindi di stabilire una dipendenza precoce. È fondamentale agire fin dall’infanzia, per evitare comportamenti dannosi per la salute, come il consumo di sigarette e alcolici. I giovani devono essere incoraggiati ad adottare sani stili di vita.

Obiettivo. Lo scopo dello studio è duplice. In primo luogo, aumentare la conoscenza nei bambini di età compresa tra i 9 e i 10 anni degli effetti negativi sulla salute del fumo di sigarette e del consumo di alcolici. In secondo luogo, introdurre e rafforzare le life skills per imparare ad affrontare le pressioni sociali che incoraggiano gli adolescenti a iniziare a fumare e bere alcolici.

Metodi. Lo studio pilota, un field **trial** randomizzato, è stato condotto nel maggio-giugno 2017. Quattro quarte elementari di una scuola primaria a Roma sono state randomizzate in un gruppo di intervento e uno di controllo. Entrambi i gruppi hanno partecipato ad una presentazione sui rischi e le conseguenze del consumo di sigarette, alcolici e sulle life skills. Il gruppo di intervento ha partecipato a due sessioni di gioco, ciascuna della durata di 1,5 ore. I bambini sono stati coinvolti in sei giochi con l’obiettivo di consolidare le conoscenze delle tematiche in studio. Un questionario multi-risposta di 21 domande è stato consegnato ad entrambi i gruppi all’inizio e alla fine dello studio. Undici domande erano sul fumo; cinque domande sull’alcol; cinque domande sulle life skills. Ogni domanda prevedeva un’unica risposta corretta. Per ogni dominio, è stato calcolato un punteggio complessivo (score totale; score fumo; score alcol e score life skills).

Risultati. 67 bambini hanno partecipato allo studio (34 nel gruppo di intervento e 33 nel gruppo di controllo). L’analisi univariata ha mostrato differenze significative nel gruppo di intervento prima e dopo l’intervento per il punteggio totale ($p < 0.001$), quello sulle conoscenze del fumo ($p < 0.001$) e il punteggio sulle life skills ($p = 0.003$). Nessuna differenza significativa nel **il** gruppo di intervento prima e dopo l’intervento è stata segnalata per il punteggio sull’alcol ($p = 0.076$). Per quanto riguarda il gruppo di controllo, l’analisi univariata ha mostrato differenze significative nel punteggio totale ($p = 0.001$) e nel punteggio delle life skills ($p = 0.005$). L’analisi multivariata ha rivelato che la partecipazione all’intervento era l’unica variabile che aveva un’influenza significativa positiva sul punteggio della conoscenza sul fumo ($\beta = 1.070$, $p = 0.05$).

Conclusioni. Questo studio pilota dimostra che l’intervento è stato efficace nel il gruppo di intervento per il punteggio totale, punteggio delle conoscenze del fumo e life skills, ma inefficace per l’alcol. Nel complesso, la combinazione della presentazione e dei giochi è stata efficace nell’aumentare la conoscenza delle life skills.

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