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"Leo&Giulia standing for public health": an animated series to promote the values of public health among school-aged children. Best practices and field-trial protocol

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Abstract

Background. *The "Leo&Giulia standing for public health" project is an innovative digital health education model targeting primary school children. The project, developed during the COVID-19 pandemic, aims to educate primary school-aged children about public health issues through an animated cartoon series. It highlights the importance of early-life health promotion and the potential role of educational settings in shaping health behaviours.*
Study design. *A 2-year school-based cluster-randomized controlled community trial will be conducted among 8-10-year-old pupils in the province of Pavia, Northern Italy.*
Methods. *The intervention group will receive an educational programme via a new episode of "Leo&Giulia" animated series, focusing on smoking prevention. The study will assess changes in knowledge, attitudes towards smoking, and communication about smoking risks among peers and parents. The trial involves baseline and follow-up assessments through questionnaires targeting both children and parents.*
Results (expected). *We assume that children in the intervention group will demonstrate increased knowledge and awareness of smoking-related health risks and develop negative attitudes towards tobacco use compared to the control group. Enhanced communication about tobacco harms among peers and between children and parents, as well as increased parental involvement in anti-smoking socialization practices, are expected secondary outcomes.*
Discussion and Conclusions. *"Leo&Giulia" integrates health education into the school curriculum, leveraging the appeal of animated content to engage children in public health topics. The project is expected to contribute to the field of health education by demonstrating the effectiveness of digital health interventions in childhood, foreseeing potential long-term impacts on health behaviors and in shaping future public health strategies.*

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Introduction

Good health has its foundations early in life. The lifestyles we adopt in childhood and adolescence, and the health risks we are exposed to, have substantial impacts on our health and wellbeing in adulthood, besides the immediate effects in childhood (1,2). Therefore, health promotion targeting children has the potential to contribute to their development into healthier, resilient adults (3). As encouraging healthy lifestyles and health literacy at young ages benefits future health status (4), effective education program should aim to provide schoolchildren with the cognitive and psychological skills that might help them cope with transitions and emergencies, adopt healthy behaviors, and hold out against peer pressure into starting rule-breaking and maladaptive habits (5–8).

The COVID-19 pandemic underlined the importance of collective health prevention, health education and communication (9,10). Despite the consequences on children's daily lives (11) of non-pharmaceutical interventions (NPIs), such as quarantines and self-isolations, school closures, physical distancing, mask-wearing, and respiratory etiquette, during the emergency scant efforts were devoted to designing and delivering effective communication directly to children, the adults of tomorrow, especially at the school level (12).

As we firmly believe that messages of evidence-based health education can effectively address all ages (13,14), in the last few years, we have been working on developing innovative digital health education audio-visual models to teach primary school-aged children about public health, so as to empower them to adopt healthy behaviors. "Leo&Giulia standing for public health" project (15) consists of an animated series of cartoons developed to convey scientific contents to children on different public health topics, connecting medical language and arts. It was conceived by public health experts from the University of Pavia and Vita-Salute San Raffaele University of Milan, in collaboration with the Italian National Institute of Health, during the acute phase of the COVID-19 emergency. The first episode (released on April 10, 2020) (16) focused on COVID-19. It relayed important scientific and medical messages related to the viral transmission and societal consequences of NPIs adopted at the national level. The cartoon explained what SARS-CoV-2 is, how it is transmitted and why containment measures (i.e., school closures and physical distancing) were needed. Contents and dialogues were written by a scientific committee composed of public health, pediatrics, infectious diseases, neuroscience, and communication experts. Our scope was to illustrate to the school-aged population why they were called to adopt new and unusual lifestyles (i.e., staying at home for weeks, adapting to new teaching methods, giving up socializing with peers) and how to try to contain the epidemic in schools and at the community level (17). Since then, the project has competed for and won a grant from the Italian Ministry of University, which allowed the release of a second episode on March 28, 2022 (18). It focused on vaccines and immunization, explaining to children how vaccines work and protect against infectious diseases, what herd immunity is and why high vaccination coverage rates are needed to safeguard collective health. The specific aim is to provide the scientific basis for behavioural and public health rules to be adopted to guarantee a safe school reopening.

The Italian Ministry of Health and the National Institute of Health supported the project, which received funding within competitive grants. National and international scientific societies, including Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica (SItI), Società Italiana di Pediatria (SIP), Federazione Italiana Medici Pediatri (FIMP), EUropean Public Health Association (EUPHA), Association of Schools of Public Health in the European Region (ASPHER), Association of Schools and Programs of Public Health (ASPPH), Institute of International Education (IIE) endorsed the project's content and promoted its dissemination. Both "Leo&Giulia" episodes were doubled in English (19,20) and sign language (21) and were a great success, being widely distributed through traditional and social media at the national and international levels (22–24). The English version of "Leo&Giulia" (19) was awarded the best Fulbright Fellows' contribution to the fight against COVID-19 and presented at the Italian Embassy in Washington DC, USA, on the occasion of the 75th anniversary of the Fulbright program (25).

The "Leo&Giulia" serial project aims to translate evidence-based scientific messages into a language easily understandable by children (26) in order to increase youth engagement in shared public health values. Moreover, strengthening school settings as strongholds for prevention amidst society could be a successful move to build healthy cohorts of future adults, prone to contaminate peers and current adults with healthy lifestyles (27). We believe it is now time to test the effectiveness of the "Leo&Giulia" health education model in experimental settings. We propose to conduct a cluster-randomized controlled

community trial to address relevant collective health challenges within and beyond the pandemic context by increasing children's knowledge and attitudes toward healthy lifestyles. In particular, we want to focus on early prevention of smoking among children.

Although tobacco smoking is the single greatest preventable cause of death in the world and tobacco control remains a major public health challenge, inconclusive evidence is available on the scope and rationale for preventing smoking initiation and its determinants early in life. Despite the American Lung Association recommending starting smoking prevention in children younger than 12 (28), we could retrieve little data in the literature on effective health promotion interventions against tobacco targeting this age group. A rigorous systematic review based on 134 trials found that school-based program reduced smoking initiation by about 12% (29). The most effective program focused on increasing knowledge and awareness of tobacco health risks, developing social competence (problem-solving and decision-making skills) and resisting social influences (increasing awareness of peer pressure and other influences that promote substance use). However, only three of the included studies focused on children younger than 12, and none tested digital or audio-visual-based health education interventions (29).

There is great potential to invest in integrating health prevention and promotion against major behavioral risk factors into educational settings, building on the potential of new digital instruments. With "Leo&Giulia", we aim to demonstrate that children are to be engaged as independent, empowered, and informed health actors.

Methods

Objectives

"Leo&Giulia" will be implemented as a comprehensive digital educational tool for health promotion among children. Our general aim is to test the hypothesis that early prevention of tobacco smoking has positive impacts on children and their households.

First, building on the success of "Leo&Giulia" first two episodes, we aim to estimate an evidence-based cartoon series' real-world effectiveness in promoting preventive behaviors. Second, since there is robust evidence of the high prevalence of early tobacco smoking initiation and its damaging effects (30), our purpose is to increase children's knowledge of this harmful addiction and encourage antismoking skills in order to postpone tobacco smoking onset and eventually build a smoke-free cohort of future adults. Thus, our design includes the identification of potentially modifiable demographic, socioeconomic and health-related determinants of lacking awareness about smoking risks in children (31). Third, our objective is to stimulate peers and parents-children communication to prevent the development of positive attitudes and beliefs on smoking and incentivize refusing cigarettes (i.e., antismoking socialization practices) (32), given that peer pressure and family influence are crucial determinants for smoking initiation (33–35). We also plan to assess whether an awareness intervention on children could influence smoking habits by promoting non-smoking behaviours among family members. Finally, our large-scale goal is to facilitate health promotion in educational settings, being schools ideal for fostering individuals' health education (36–38)

Study design and participants

To reach the above-listed objectives, the "Leo&Giulia" project will be developed as a 2-year school-based cluster-randomized controlled community trial (39–41) conducted among primary school pupils aged 8-10 years in the province of Pavia, Northern Italy. The intervention group will attend an educational program and be compared with the control group not receiving it.

Public primary schools, adhering to the regional-level program "Schools Promoting Health" (https://www.scuolapromuovesalute.it/), that agree to participate in the trial will be randomized to the intervention or control group; cluster randomization will ensure to avoid potential experimental contamination related to school setting. Within each school, all children attending the 3rd or 4th grade will be eligible. Written informed consent will be collected from pupils' parents. The trial will be registered on ClinicalTrial.gov.

The experimental phase will be structured as follows (Fig. 1): i) baseline assessment questionnaire (1st week); ii) intervention (2nd week); iii) follow-up (6th month). During the 1st week (T0) of the educational program, children from both intervention and control groups will be administered in their classrooms the baseline assessment paper-based questionnaire, including items on the predefined outcomes. Children will be given a closed envelope containing the baseline assessment paper-based questionnaire targeting their parents for the collection of sociodemographic variables, family composition and characteristics, and

selected outcomes. During the 2nd week (T1), for both groups, parents' questionnaires will be gathered. Only for classes randomized to the interventional arm, the audio-visual educational tool will be administered, followed by a Q&A session with a public health expert. The understanding and appreciation levels of the cartoon will be assessed via a satisfaction survey. After six months (T2), a follow-up assessment questionnaire, examining the previously investigated outcomes, will be administered to children in classrooms to test the short-term effectiveness of the intervention. The follow-up parents' questionnaire will be handled with the same 1st-week baseline assessment procedures.

A pilot study will be conducted in order to test the educational materials. For an explorative purpose, after 12 months of follow-up (T3), a long-termed outcomes evaluation will be collected in the sample of the pilot study.

Intervention design and production

A multidisciplinary panel of experts in the fields of public health and epidemiology, pediatrics, and tobacco control will select the scientific content to be taught, while communication and psychology experts will modulate the evidence-based messages into age-appropriate language. They will jointly write the cartoon script. The proposed third episode of "Leo&Giulia" will address the topic of the harmful effects of tobacco consumption on individual and population health. Specific content will be selected on the basis of available literature. On the one hand, the short-term adverse effects of smoking, such as smell, teeth stains, bad breath, decreased athletic performance, and quickly developing addiction, will be emphasized. On the other hand, among long-term consequences, the cartoon will highlight the impacts on health, including cancers and heart attacks, the illegal act of buying cigarettes when underage and related costs, diverting economic resources (42).

The cartoon will be produced by an animation studio specialized in the creation and production of computer-animated video content in the scientific field. The project's Scientific Committee will supervise the production process through discussion sessions in which scientists, psychologists, communication experts and artistic directors collect ideas and share proposals.

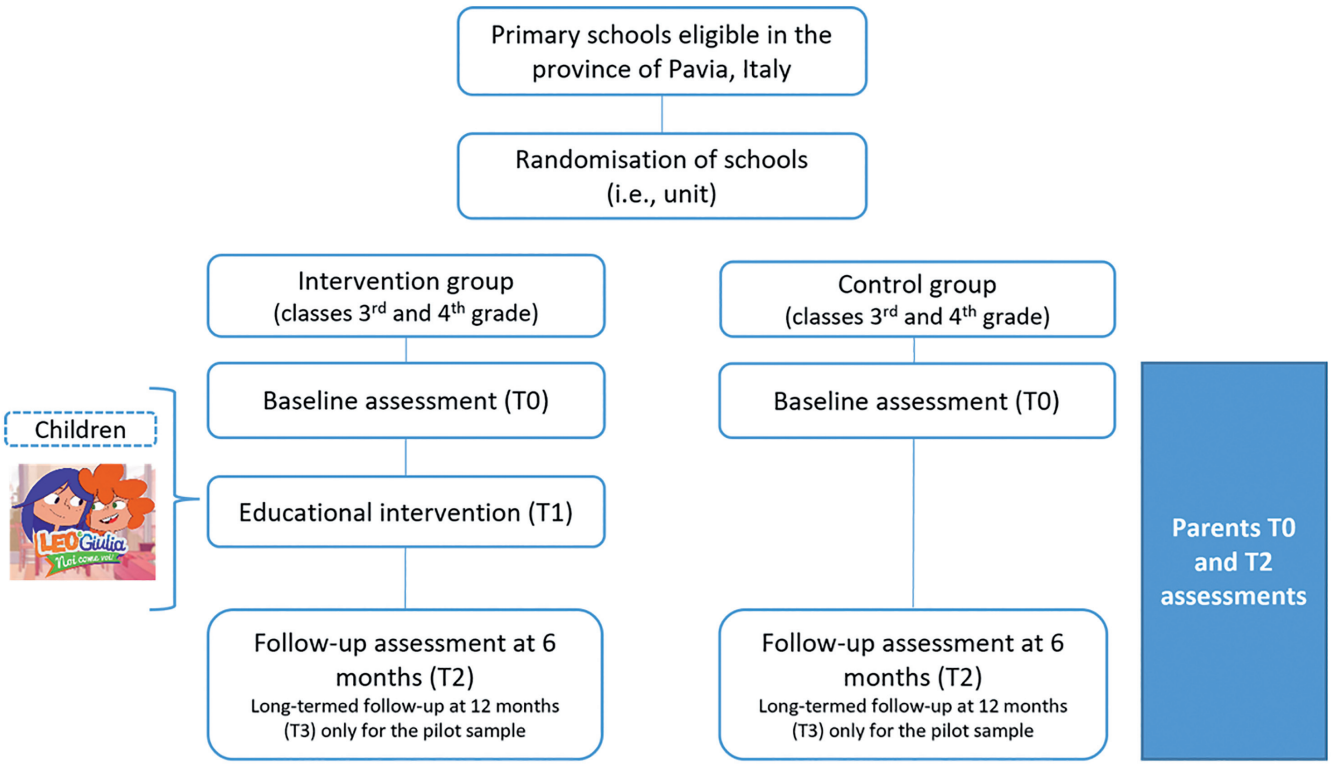

Figure 1. Leo&Giulia trial: flowchart of the study design (Video and images available from: https://youtu.be/UWJ6MqZuQ20?feature=shared accessed: 19.01.24).

Outcomes

Primary outcomes of interest will include the changes in knowledge and awareness of smoking-related health risks, and attitudes towards smoking in the intervention group compared to the control group. As secondary outcomes, rates of changes in peers and parents-children communication about smoking and parental antismoking socialization, smoking rules at home and family members' smoking habits will be compared between the two groups.

Questionnaire and data collection

The questionnaire will be developed by adapting internationally and nationally validated survey tools. The Global Youth Tobacco Survey (GYTS) (43), promoted by the Regional Office for Europe of the World Health Organization (WHO), designed to monitor health-risk behaviors in youth onset, will be integrated by available literature on the specific outcome to be investigated (44–46). Data to derive primary and secondary outcome measures will be collected at baseline (T0), after six months of follow-up (T2), and, only for the explorative purpose, at 12 months (T3). Sociodemographic, individual and contextual variables will also be collected at baseline (T0), including family composition, age, country of origin, parents' education and occupation, health literacy, children's school performance, adverse experiences (divorced/separated parents, deaths, etc.), learning disabilities, home restriction policies and communication style, children's and relatives' chronic illnesses.

Data will be collected at the individual level from children and at the household level from parents. During school time, children will be asked to answer an in-person paper-based questionnaire administered by trained personnel. Household data will be collected through self-administered paper-based questionnaires for parents, accounting for diverse family compositions.

Sample size calculation

Sample size calculation was conducted considering that the randomization units were clusters (i.e., schools) rather than single individuals. The expected prevalence of antismoking attitudes was estimated at about 70% based on literature (44,46). An increase of at least 20% in the prevalence of antismoking attitudes in the intervention group compared to the control group was considered worthy of documentation. Assuming randomization units of about 40 individuals (i.e., 2 classes per school) and variability among clusters of about 20%, it was calculated that nearly 500 children for each study arm need to be recruited to reliably document the expected difference (error = 0.02, ß error = 0.1).

Randomization

Centralized randomization will be employed with stratification by the number of children per school and geographic area (i.e., postal code). We will randomly assign schools to the intervention and control groups to reduce the chance of selection bias. Participants will be taken blind into the randomization plan.

Statistical analysis

We will carry out descriptive analyses of baseline characteristics and study outcomes, comparing results between the intervention and control groups. To assess the effectiveness of the intervention, we will analyze individual differences (among children and parents) between the two arms through multilevel generalized linear models. Stratified analyses will also be performed according to demographic, socioeconomic and health-related determinants. We will consider adjustments for the cluster sampling design estimating the intra-class correlation, besides adjustments for potential covariates at baseline (including sociodemographic characteristics of the family).

Results (expected)

In terms of expected outcomes, we hypothesize that children exposed to the audio-visual intervention will demonstrate greater knowledge and awareness of smoking-related health risks and negative attitudes against tobacco products compared to their counterparts in the control group. We expect that children in the intervention group, compared to controls, will communicate more on tobacco harms not only among peers but also with parents, who in turn will engage more actively in anti-smoking socialization practices and, for those who smoke, adopt stricter household smoking rules and potentially reduce their smoking habits.

Our project will contribute significantly to the field of health education by promoting an innovative digital-based model targeting primary-school children, demonstrating the potential of intervening early in life (i.e., childhood) to encourage healthy behaviors, strengthening the role of schools and, more in general, educational settings for wellbeing promotion and fostering children to pro-actively influence their household's health attitudes and behaviors.

Discussion

The "Leo&Giulia" project aims to elevate awareness and attitudes towards smoking and its associated health risks among primary school children, thereby fostering an environment conducive to health promotion and prevention. Our project is poised to yield significant results. Firstly, the creation of a new episode of "Leo&Giulia" will not only contribute to our scientific understanding but also offer an engaging tool for health education, accessible both nationally and internationally. Furthermore, our rigorous trial methodology intends to set a benchmark for future research, available to other groups to assess further questions. Of note, the project aims to generate real-world, comparative data on the effectiveness of "Leo&Giulia", enriching the scientific literature and potentially influencing future health education strategies. We also anticipate the establishment of enduring collaborations with schools and educators, facilitating ongoing health promotion efforts and potentially extending the follow-up times in order to collect data on smoking initiation rates in the two study arms and, thus, offering insights into the long-term effectiveness of the intervention. Moreover, the project supports integrating public health principles within educational settings, leveraging the unique position of schools in shaping children's health behaviors.

The project will contribute to the development of an emerging field of research on the social determinants of health and, specifically, innovative health education models to improve them in children. It will help develop data, theory, and methodology needed to better assess the effectiveness of such models and understand public policy and practice options for acting on education to promote health and wellbeing.

By targeting behavioral determinants of health in children, we aim to influence the future health landscape. The project aims to generate relevant evidence about the impact of innovative interventions on smoking attitudes and knowledge among schoolchildren, the adults of tomorrow. Measuring, analyzing, understanding and interpreting relevant data related to the most considerable behavioral risk factor for mortality and morbidity is key to planning additional trustworthy prevention program, informing sound communication campaigns and envisioning effective solutions for collective health promotion. The expected direct and indirect impacts will determine positive returns protecting in the long run population health and reducing the behavioral-related burden on the healthcare system. Moreover, strengthening schools' role as strongholds for prevention amidst society could be a successful move to build healthy cohorts of future adults acting as independent health actors. Indirect potential beneficiaries of broader community benefits could include children's household members, such as older brothers and sisters, parents and grandparents. They might be called both to create a smoke-free environment for children and, in the case of smokers, be encouraged to quit smoking.

Even though cartoon animation does not represent an innovation, producing an animated series dedicated explicitly to schoolchildren addressing the needs of school health education curricula is a brand-new approach. Early-age health education would greatly benefit from the seriality of the cartoons, the acquaintance with the characters and the robust evidence-based scientific content of the conveyed messages. Moreover, using 2D high-quality and artistic animation techniques will ensure the complete permeation between visual arts and medical language.

However, our study is not without limitations. The generalizability of our findings may be constrained by the specific cultural and educational context within which the study is conducted. Additionally, the short duration of the intervention and follow-up period may limit our ability to assess the long-term effects and sustainability of the observed changes in attitudes and behaviors. Furthermore, parental involvement, a crucial component of the intervention, may vary widely, potentially influencing the effectiveness of the intervention.

Conclusion

In conclusion, following the path traced by the previous episodes of "Leo&Giulia" and their wide appreciation, the project exploits a new pattern of educating children (and, indirectly, parents) about healthy habits and lifestyles, benefiting from the advantages offered by the use of a digital tool, highly accepted amongst children. This foresees the long-term approaches that could change how stakeholders come close to the planning of health promotion interventions, as well as could drive other researchers towards entirely new directions in designing public health strategies for the years to come.

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Statements and declarations

Competing interests

Each author declares that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangement) that might pose a conflict of interest in connection with the submitted article.

Riassunto

"Leo&Giulia standing for public health": una serie animata per promuovere i valori della salute pubblica tra i bambini in età scolare. Modello e protocollo sperimentale

Introduzione. Il progetto "Leo&Giulia standing for public health" rappresenta un modello innovativo di educazione sanitaria digitale rivolto ai bambini della scuola primaria. Sviluppato durante la pandemia di COVID-19, il progetto mira a educare i bambini in età scolare sui temi della salute pubblica attraverso una serie di cartoni animati. Esso sottolinea l'importanza della promozione della salute in età scolare e il potenziale ruolo degli ambienti educativi nel plasmare stili di vita e comportamenti.

Disegno dello studio. Un trial di comunità controllato e randomizzato a *cluster* della durata di 2 anni verrà condotto nelle scuole della provincia di Pavia, coinvolgendo alunni tra gli 8 e i 10 anni.

Metodi. Al gruppo di intervento verrà proposto un programma educativo basato su un nuovo episodio di "Leo&Giulia", incentrato sulla prevenzione del fumo di tabacco. Lo studio valuterà i cambiamenti nelle conoscenze e attitudini verso il fumo e la comunicazione sui rischi del fumare sia tra coetanei che con i genitori. Il trial prevede la somministrazione ripetuta (*baseline* e *follow-up*) di questionari rivolti ai bambini e ai genitori.

Risultati (attesi). Il risultato atteso è che i bambini inclusi nel gruppo di intervento acquisiscano una maggiore conoscenza e consapevolezza dei rischi legati al fumo rispetto al gruppo di controllo. Lo studio sperimentale quantificherà inoltre l'impatto indiretto dell'intervento sulle famiglie, valutando la comunicazione tra coetanei e con i genitori relativamente ai danni causati dal fumo di tabacco.

Conclusioni. "Leo&Giulia" mira ad integrare l'educazione sanitaria nei programmi scolastici, sfruttando l'attrattiva dei contenuti animati per coinvolgere i bambini sui temi di salute pubblica. Il progetto vuole dimostrare l'efficacia degli interventi di salute digitale in età scolare e prevede impatti potenzialmente a lungo termine sui comportamenti sanitari e nella definizione delle future strategie di educazione sanitaria.

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