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Reducing social inequalities in access to overweight and obesity care management for adolescents: The PRALIMAP-INÈS trial protocol and inclusion data analysis

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ABSTRACT

Background: Despite social inequalities in overweight/obesity prevalence, evidence-based public health interventions to reduce them are scarce. The PRALIMAP-INÈS trial aimed to investigate whether a strengthened-care management for adolescents with low socioeconomic status has an equivalent effect in preventing and reducing overweight as a standard-care management for high socioeconomic status adolescents.

Methods: PRALIMAP-INÈS was a mixed, prospective and multicenter trial including 35 state-run schools. It admitted overweight or obese adolescents, age 13–18 years old, for 3 consecutive academic years. One-year interventions were implemented. Data were collected before (T0), after (T1) and post (T2) intervention. Among 2113 eligible adolescents who completed questionnaires, 1639 were proposed for inclusion and 1419 were included (220 parental refusals). Two groups were constituted according to the Family Affluence Scale (FAS) score: the less advantaged (FAS ≤ 5) were randomly assigned to 2 groups in a 2/1 ratio. The 3 intervention groups were: advantaged with standard-care management (A.S, n = 808), less advantaged with standard-care management (LA.S, n = 196), and less advantaged with standard and strengthened-care management (LA.S.S, n = 415). The standard-care management was based on the patient education principle and consisted of 5 collective sessions. The strengthened-care management was based on the proportionate universalism principle and consisted of activities adapted to needs.

Inclusion results: The written parental refusal was less frequent among less advantaged and more overweight adolescents. A dramatic linear social gradient in overweight was evidenced.

Discussion: The PRALIMAP-INÈS outcomes should inform how effectively a socially adapted public health program can avoid worsening social inequalities in overweight adolescents attending school.

Trial registration: ClinicalTrials.gov (NCT01688453).

1. Background

Over the last decades, most high-income countries have experienced a substantial increase in the proportion of children and adolescents who are overweight or obese [1]. The prevention of obesity in adolescents is a national priority in France [2]. Overweight/obesity in adolescence

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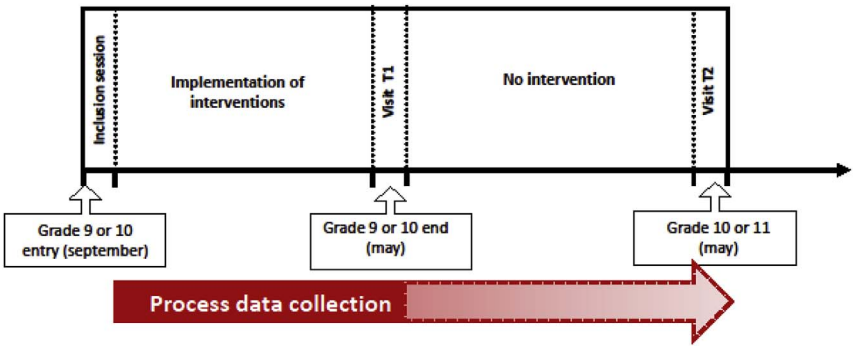

Fig. 1. PRALIMAP-INÈS implementation.

and unfavorable health behaviors likely persist into adulthood [3]. Being overweight in adolescence has been identified as the best predictor of adult obesity [4]. Adolescence is a crucial phase of the life cycle and should be targeted to prevent the development and persistence of obesity [5].

In this context, the PRALIMAP trial was implemented between 2006 and 2010 in 24 state-run high schools in France to evaluate the effectiveness of 3 overweight and obesity prevention strategies (educational, screening and environmental) [6]. A structured screening strategy led to a significant decrease in overweight and obesity prevalence. Indeed, the 2-year change in outcomes was more favorable in the 12 screening and care high schools than the non-screening ones [7–9]. The PRALIMAP data identified major social inequalities in overweight and obesity frequency in adolescents at grade 10 entry [10]: nutritional knowledge and behaviors and body size indicators were less favorable (for example in adolescents for whom their parents or legal guardian were employees or workers (obesity 5.1% vs 2.6%)).

Obesity is increasingly recognized worldwide as a social public health problem, and social disparities remain unabated in recent years, both for children and adults. Income is inversely related to obesity prevalence [11]. The social gradient is visible between countries but also within countries and is clearly evidenced whatever the socioeconomic measurement: profession, level of education, family income and even perception of wealth. In 1997, the obesity prevalence among the poorest segment of the French population was 2.4 times that of the richest segment, this figure rising to 2.9 in 2012 [12].

The reasons for the widening health inequality gap remain elusive. The main modifiable risk factors for overweight and obesity (unhealthy diet, physical inactivity, etc.) are more common in socially disadvantaged than advantaged populations, both for adults and adolescents [13]. However, more indirect factors may also be involved. Public health interventions may actually increase health inequalities. People who are vulnerable to obesity derive less benefits from interventions than those who are not vulnerable [14].

Therefore, we need interventions that explicitly intend not to widen health inequalities but to tackle the different restraints induced by a socially less-advantaged context. The proportionate universalism idea appears to be a solution by implementing universal prevention activities addressing the whole population (universalism) and acting on each population category according to their needs (proportionality) [15]. However, the features of such interventions have yet to be validated and research on this topic is urgently needed [16–18].

The objectives of the PRomotion de l'ALIMentation et de l'Activité Physique - INÉgalités de Santé trial (PRALIMAP-INÈS) were to evaluate the effectiveness of a school-based intervention to address social inequalities in adolescents who are overweight and the impact of the interventions on adopting healthy behaviors, quality of life, anxiety and depression.

2. Methods

2.1. Design of the PRALIMAP-INÈS trial

The trial was based on three 2 × 2 non-independent comparisons: 1) strengthened-care management strategy for adolescents at low socioeconomic status vs standard-care management for those with high socioeconomic status (equivalence); 2) standard-care management for adolescents at high versus low socioeconomic status (superiority); and 3) strengthened-care vs standard-care management for adolescents at low socioeconomic status (superiority). PRALIMAP-INÈS was a mixed (partly quasi-experimental by socioeconomic status and partly experimental randomized with two-thirds and one-third socially less-advantaged adolescents) prospective and multicenter trial of overweight and obese adolescents aged 13 to 18 targeting grades 9 of middle school and 10 of high school for the academic years 2012–2013, 2013–2014 and 2014–2015.

The interventions were implemented during 1 academic year, and follow-up consisted of 3 visits over 2 academic years (Fig. 1). The PRALIMAP-INÈS trial has been approved by the French consultative committee for treatment of information in health research (no. 12.299), the French National Commission for Data Protection and Liberties (no. 912372) and the French Persons Protection Committee (no. 2012/15). This trial was registered at ClinicalTrials.gov (NCT01688453).

2.2. Study setting and school recruitment

The only eligibility criterion for schools was to be one of the 61 state administrative establishments in the Vosges department (North-Eastern France). All 22 high schools participated: 7 general and technological, 12 vocational and 3 mixed (general, technological and vocational courses). All had yet to meet the objective "Promoting the adolescents' health as a success condition" including the battle against overweight and physical inactivity, in the 2010–2013 academic project [19]. In 2013–2014, 13 middle schools were committed to the project after a special request to 39 by the steering committee. In total, 35 schools participated.

2.3. Recruitment and randomization

Adolescents were recruited in 3 waves (2012–2013, 2013–2014 and 2014–2015 academic years). During the first weeks of the recruitment year, an inclusion session was organized in each school by close collaboration between the school and the research teams. The school provided a dedicated area with 3 rooms equipped with inter-connected computers with an autonomous Wi-Fi network allowing for real-time sharing information between professionals and adolescents (for anthropometric measurements, questionnaires and medical visits). The following 3 steps were required to identify adolescents who met inclusion criteria (Fig. 2).

- Anthropometric measurements for eligibility

In the 2012–2013 academic year, adolescents were invited to declare in writing their weight and height. If the body mass index (BMI) was greater than the International Obesity Task Force (IOTF) [20] thresholds for overweight reduced by 1 kg/m^2 for age and gender or if the information was missing, the adolescents were invited to the inclusion session. Thereafter, all adolescents were invited to the inclusion session.

The invited adolescents were measured (weight, height and waist circumference) by trained school nurses and/or clinical research nurses. If the immediate computer-calculated BMI was greater than the IOTF [20] thresholds for overweight reduced by 1 kg/m^2 for age and gender and/or the waist circumference was greater than the McCarthy cut-off values for age and gender [21], the adolescent was invited to proceed with the next step.

- Self-administered questionnaire collection

The eligible adolescents were asked to complete questionnaires directly on the computer to collect the following information.

Sociodemographic characteristics: Data were collected on date of birth, gender, grade, social and professional class of the family head at entry of the adolescent into grade 9 or 10, school boarding status (non-boarder, half-boarder or full boarder), parents' occupational status, adolescent's perception of their parents' weight status and physical activity practice, and family income, as well as the WHO Family Affluence Scale (FAS) score [22]. FAS was used to define the social level through four simple questions exploring availability of a personal bedroom, of family cars and computers and opportunities for family holidays. It provided a score ranging from 0 to 9 and was then dichotomized: an "advantaged" social level was FAS score > 5 and a "less advantaged" level was FAS score ≤ 5 (merging the low and medium classes proposed by Boyce W et al. [23]). Sociodemographic data (social and professional class of family head, residence code and family composition) were compiled from the Board of Education database but were not available at inclusion for social status appreciation but only by midyear.

Lifestyle and nutritional (diet and physical activity) attitudes and behaviors: Diet was measured by a food frequency questionnaire [24]. Physical activity and sedentary behavior were measured by the International Physical Activity Questionnaire (IPAQ) [25]. Alcohol and tobacco consumption were investigated. An additional question explored the adolescent's needs for excess weight management.

Health: The EAT-26 [26,27], a self-administered questionnaire with responses on a Likert scale ranging from 0 (never) to 6 (always), screened for anorexic and bulimia symptoms. The Hospital Anxiety and Depression scale (HAD) [28,29] screened for anxiety and depression symptoms with 14 items on a 4-point Likert scale (range 0–3). The Kidscreen [30], a 10-item generic self-administered questionnaire explored perceived health and quality of life.

- Medical visit

Physicians reviewed the anthropometric measurements and questionnaire results on a dedicated computer. They checked the previous measurements, re-measured the adolescent (weight, height, and waist circumference) as required and finally confirmed or not the weight excess. The weight excess was defined by BMI greater than the IOTF [20] for age and gender and/or a waist circumference greater than the McCarthy cut-off values for age and gender [21]. If the weight excess was not confirmed and no eating disorder was suspected (overall EAT-26 score greater than the 17 cut-off values recommended by the authors [31]) and the adolescent did not request excess weight management, the physician simply explained the results and entered the weight, height and BMI scores in the adolescent health book. If the weight excess was confirmed according to the anthropometric criteria but was disconfirmed by the clinical examination (athletic adolescent) and if the overweight history and if the adolescent situation were judged not appropriate for intervention, the physician explained the results and might refer the adolescent to the general practitioner (GP). If the weight excess was confirmed, an eating disorder was suspected, or the adolescent requested excess weight management, the physician then explained the results of the different measurements and entered weight, height and BMI scores in the adolescent health book; collected any necessary additional information (name of the family doctor, history of overweight, motivations etc.); and proposed that the adolescent be included in the care program implemented in the school.

Once the social status was defined, the computer software automatically allocated the adolescent to the intervention: if the social status was "advantaged", the adolescent was allocated to the standard-care management, advantaged with standard-care management (A.S); if the social status was "less advantaged", the adolescent was randomly assigned as follows: one third to standard-care management, less advantaged with standard-care management (LA.S), and two thirds to strengthened-care management, less advantaged with standard and strengthened-care management (LA.S.S). We performed a block (size 6) randomization stratified on the school.

- Ethics, consent and permissions

The physician gave the adolescent 3 letters showing the results of the different measurements: one for the adolescent, one for the parents (including a reply slip for refusing or accepting the proposal to be in the trial) and one for the GP. The adolescent was included in the trial unless parents expressed a written refusal for participation in the interventions.

2.4. Interventions

Standard-care management, according to the validated PRALIMAP trial [7] was proposed for all adolescents, while strengthened-care management intending to address barriers was proposed for only socially less-advantaged adolescents of the LA.S.S group. The activities of strengthened-care management were developed and validated during a multidisciplinary workshop that took place on April 3, 2012 and brought together researchers and experts in nutrition, physical activity and health inequality as well as health professionals and school staff.

A logic model guided the planning and execution of the PRALIMAP-INÈS interventions. The logic model allowed the research team to systematically identify essential resources needed for implementing all program activities and to consider related, specific anticipated outcomes. Each component included activities and indicators to allow for evaluation. The logic model also created a pictorial map of entities participating during the planned year of the program. It also provided a framework during the intervention years and subsequent program implementation. An additional table file displayed the model in more details [Supplemental file 1].

2.4.1. Standard-care management

Five 2-hr sessions were scheduled around the themes of healthy eating and physical activity. They were led by a multidisciplinary team including a dietician, a psychologist and a professional in physical activity. These professionals belong to a health network specialized in the management of overweight and obesity in adolescence (Association Vosgienne des Réseaux de Santé [AVRS], UFOLEP, Profession Sport Animation, Saphyr). The sessions were set up in each school with upstream planning to account for the specificities of the schools. The school nurse was invited to contribute to the sessions. The adolescents were reminded to participate in sessions via text message (SMS) sent by the Local Health Insurance Fund of Vosges. The intervention logic was to progressively move adolescents to independence to overcome various obstacles. The sessions involved acquisition and/or maintenance of skills to better understand healthy eating and physical activity aspects and welfare; support to formulate micro-objectives; critiquing their

Table 1
Objectives to be achieved by adolescents during the collective sessions.

Themes	Objectives
Session 1	Getting to know the group and the participants, taking note of the guidelines of each session
Who am I?	Identifying my food and physical activities perception
	Understanding what excess weight, BMI, and energetic balance are
	Expressing my own concerns, needs, and expectations
Session 2	Sharing a definition of physical activity/sedentary behavior
My physical activity passport	Assimilating the advantages and benefits of physical activity
	Discovering both the qualitative and the quantitative requirements for physical activity participation
	Understanding and evaluating my physical activities and sedentary behavior
	Participating in a physical activity and expressing my feelings about it
Session 3	Discovering both the qualitative and quantitative requirements set by the National Nutrition and Health Programme for healthy eating
My diet tips	Understanding my eating habits
	Taking a critical look at my daily menu
Session 4	Knowing the strategies to deal with difficult situations
My landmarks, my changes	Understanding the role of social interactions in the construction of self-esteem and self-assertion
	Defining the objectives of and the conditions for changing nutritional habits
Session 5	Identifying the factors influencing my choices regarding food and physical activity
My projects	Elaborating my decisional balance with regard to physical activity and food
	Committing to achieve nutritional goals

own practices; the use of tools and animation techniques enhancing autonomy and sense of self-efficacy.

The objectives adolescents might achieve during the collective sessions are in Table 1.

2.4.2. Strengthened-care management

Adapted activities were offered to less-advantaged adolescents for overcoming barriers attributable to health inequalities in diet and physical activity behaviors.

- **Oral invitation and explanation**

To overcome barriers to writing, parents were contacted by phone by TNL Marketing before the care management activities to give them details about the PRALIMAP-INÈS trial. Next, when an adolescent was absent from an activity, the family was contacted to encourage participation in the next sessions and to understand the reasons for non-participation.

- **Multidisciplinary team (MDT) meetings**

The MDT meetings were elaborated on the model developed in oncology care management [32]. The MDT meetings aimed at changing professionals' perceptions and practice regarding less-advantaged adolescents. Each meeting gathered together PRALIMAP-INÈS trial professionals, school medical doctors and nurses; AVRS dieticians, psychologists and physical activity practitioners; specialized obesity professionals; and if available, the adolescent's GP. Three meetings were held to propose and follow up activities adapted to the adolescent's needs.

At the first meeting, the weight history of the adolescent and sociodemographic and school characteristics were presented and shared, relying on the data collected during the adolescent's inclusion and the first collective session in addition to the school data. The information pooling aimed to assess the adolescent's resources, difficulties and priorities, appointed a resource person, and guided the adolescent toward one or several of the strengthened-care management activities and/or other care if necessary. The second meeting took place in the middle of the academic year and aimed to assess the activities joined by the adolescent, identified the adolescent's difficulties in terms of the key determinants of social and health inequalities, made adjustments if necessary and guided the adolescent toward other settings (adolescents facing great difficulties such as severe obesity, severe forms of anxiety or depression, severe eating disorders etc. were given external care and support). The third meeting took place at the end of the academic year and overall aimed to assess each care and support session as well as outline recommendations to be followed in the future by the adolescent, the parents and the GP.

- **Motivational interviewing**

Motivational interviewing was a particular type of interview based on a style of communication that specifically focuses on the person to increase personal motivation by exploring and resolving ambivalences in discourse. The benefits of motivational interviewing have been established for all therapeutic situations in which ambivalence and motivation are at the center of a change process [33]. Coping with ambivalence and building and sustaining motivation were especially difficult for less-advantaged adolescents [34]. The motivational approach is two-phased, helping the adolescent build up motivation for change and eventually strengthening the adolescent's motivation to implement change. The coaches were psychologists (MSc degree) and received special training in motivational interviewing [35]. Five sessions were offered and each focuses on a particular theme. The first session explored the general ambivalences related to change that the adolescent experiences. The second explored social relationships likely to affect the change process (social support/social pressure/self-assertion). The third session set the focus on physical activity and how physical activity was experienced, to allow a discourse of change to emerge and a decrease in resistance to change. The fourth session followed the same objectives but explored eating behaviors. The fifth and final session aimed to reinforce feelings of personal efficacy and self-esteem. The adolescent was encouraged to explore emotional management, self-control and respect of one's body through resonant breathing biofeedback (cardiac coherence), a technique in which slow regular breathing harmonizes the heart rate [36].

- **Physical activity motivational interviewing**

The interview was held face to face for a 1 h by a trained physical activity professional. Following the first MDT meeting, the adolescent was invited to the interview via a direct text message (SMS) or the school nurse. The objectives were to identify and overcome, with the adolescent, barriers to physical activity and non-sedentary lifestyle, to feel pleasure doing physical activity and to find avenues and solutions appropriate to the environment and desires. The exchange focused on addressing leisure time, passions, and projects as well as physical activity and sedentary behavior representations.

- **Sporting good and National Union School Sport (UNSS) coupon**

To overcome financial difficulties, win–win partnerships with a physical activity trading name and UNSS associations have been established. The adolescent chose a sporting good, up to a 40-Euro maximum value, including clothing and/or devices meant for a physical activity from a specifically designed catalogue. The PRALIMAP-INÈS coordination team delivered the chosen lot to the school nurse to be given to the adolescent. In every school, the UNSS association offered sport activities complementary to those of the curriculum. The residual financial participation was borne by the program with the UNSS coupon. The UNSS corresponding physical education and sports teacher in the school was encouraged to implement adapted physical activities.

- **Local physical activity directory**

To favor access to information, a leaflet was created with the help of the Departmental Direction of Social Cohesion and Populations Protection and provided the physical activities available locally along with their financial support schemes. It was mailed to the adolescent's home accompanied by an explanation letter.

The local physical activity directory constituted with the specific motivational interviewing, the sporting good and the UNSS coupon what was called the physical activity package.

- **Food workshops**

Food workshops, performed after the collective sessions, consisted of 2 sessions of 1.5 h each supervised by a dietician in school and intended for small groups of adolescents invited by the school nurse and by text message (SMS). The main activity was to prepare cheap, healthy, tasteful and enjoyable meals. The objective was to make the adolescent eat mindfully, with pleasure and without guilt or losing control, and to promote a nutritional culture and environment. Adolescents created a recipe booklet together for budget meals.

- **Peer health promotion**
  Two experimental peer education approaches were implemented to encourage healthy eating and physical activity via peer motivation. Being encouraged by peers of low socioeconomic status was expected to counteract the social and cultural differences that exist between adolescents of low socioeconomic status and the health professionals delivering the activities.
  - **Social media activities**
    A social media activity using Facebook© was offered during the 2012 and 2013 academic years. The adolescent was invited to join a dedicated Facebook© group. Two nutritional challenges, one on physical activity and one on diet, were posted on the group page on a weekly basis and the adolescent could sign up for a challenge by clicking the "like" feature of Facebook©. A point system encouraged group members to share their experiences, support other members and propose their own nutrition challenges, thereby becoming digital peers.
  - **Peer facilitators**
    Peer facilitators were selected in 2013, received training and then had to organize nutritional activities with selected peers. Peer facilitators were selected by the following criteria: an ability to control their weight as evaluated by a physician, motivation to become peer facilitators and an FAS score ≤ 5 suggesting that they were of similar socioeconomic background as the peers they would be organizing activities with. Peer facilitators received a 2-hr training at the beginning of the academic year and were assigned a small group of peers. As a group, they were encouraged to develop activities based on the common interests of each particular peer group to pursue together during the academic year. Peer facilitators were contacted by a member of the PRALIMAP-INÈS team on a regular basis for follow-up and support in the form of telephone calls as well as text messages (SMS). They were also rewarded for their time and effort with a certificate at the end of the academic year.

- **Hospital specialized management of obesity**

Implemented in the 2013–2014 and 2014–2015 academic years, hospital specialized management of obesity was proposed to the adolescent with proven obesity after the first MDT meeting. The aim was to improve access to highly specialized medicine for obesity-related problems. The first step consisted in facilitating, planning, organizing and coordinating coming to the specialized center. The travel expenses were paid by the Vosges health insurance with prevention funding. The organization and planning were performed by a coordinating nurse specially recruited for this task as part of the PRALIMAP-INÈS trial.

Once at the specialized center, the adolescent benefited from a multidisciplinary approach combining a complete biomedical check-up and an adapted care focused on patient therapeutic education. In addition to the complete biomedical examination, the adolescent underwent a full day of tests and interviews (dual energy x-ray absorptiometry; blood tests designed to detect metabolic diseases such as type 2 diabetes mellitus, dyslipidemia, liver metabolic diseases; electrocardiogram; pulmonary function tests; analysis of food practices; search for eating disorders etc.). The adolescent met endocrinologist and nutritionist, dietician and psychologist. After the check-up, a specialized care was proposed to the adolescent and the family (education in changing lifestyles, cognitive-behavioral therapies, psychological support, family therapy, etc.). Additional visits were proposed according to the check-up issues. Two specialized centers were considered referral centers for this expertise: 1) the regional specialized center of obesity care located at Nancy University Hospital (Diabetology, Metabolic diseases and Nutrition Unit) and the Diabetology and Nutrition Unit of Saint Die Hospital.

2.5. Follow-up visits

At the end of the intervention (end of grade 9 or 10), the adolescent was invited for a follow-up visit (T1). During the check-up, anthropometric measurements (weight, height, waist circumference) and self-administered questionnaires (the same as in the inclusion session plus transition questions completed for each of the outcome categories and a program participation and satisfaction questionnaire) were collected. The data collection was organized in each school on the same principle as for the inclusion session one. A post-intervention follow-up visit (T2), similar to T1, was executed (whatever school the student was in) 1 year after the end of the intervention (Fig. 1).

2.6. Process data collection

Process data, including quantitative and qualitative measures of participation and intervention delivery, was intended for estimating an intervention dose [37]. In health promotion programs, particularly those conducted within the framework of controlled trials, the level to which interventions are implemented must be considered when interpreting outcomes. Extensive process evaluation was considered a main part of the trial. It aimed to document how schools have implemented the intervention and how adolescents received it. Other process aimed were to collect information on the provision and receipt of the standard- and strengthened-care management, determine the extent of possible contamination between adolescents, and report on the experience and impact of PRALIMAP-INÈS. Thus 2 domains – implementation and participation – were explored according to quality and quantity and from 4 points of view: adolescents, mobile team of healthcare network specialized in nutrition, school professionals and research team. The process data were collected by observation, interviews, and self-administered questionnaires.

Observation: Members of the research team observed the key

processes in the intervention implementation in every school and documented the processes in activity reports. The observation included meetings with school professionals, sign-off sheets from group educational sessions and sheets reporting adverse events. Meetings were organized each year, were conducted by the PRALIMAP-INÈS team and aimed to ensure and follow up the performance of activities and uphold the dynamics of the school's investment in the process. To monitor adolescents' participation in the sessions, sign-off sheets were signed and returned by the mobile team of healthcare network specialized in nutrition. Anyone (school professional, mobile team, PRALIMAP-INÈS team etc.) could report an adverse event (i.e., difficulties attending appointments, absence from activities, refusal to participate, lack of documents) to better understand the implementation, implantation, delivery and participation in the program.

Interview: Each year, the PRALIMAP-INÈS process evaluation group used a semi-structured interview guide to independently interview school professionals (school nurses and director) and mobile team professionals. The aim was to gather information about the content, delivery and stakeholders' appreciation of the PRALIMAP-INÈS activities (i.e., what was done and how it was done, what stakeholders liked and disliked, the pros and cons of the activities, their degree of satisfaction with the program, their appraisal of the benefit for adolescents, and recommendations to improve the program).

Self-administered questionnaires: For each collective session and each individual activity, a satisfaction questionnaire was completed by adolescents. A year-specific appreciation questionnaire was included in the T1 adolescent report form. The survey aimed to explore adolescents' perception of the PRALIMAP-INÈS trial (i.e., interactions with PRALIMAP-INÈS team, health and high school professionals; participation in PRALIMAP-INÈS activities; what they liked and disliked; and how they perceived PRALIMAP-INÈS as a whole).

2.7. Data management and analysis

2.7.1. Data management quality control

A Microsoft Access-based information system was developed to warehouse data (Microsoft Access®, 2007). It allowed adolescents, nurses and physicians to directly complete data on a computer; data were then stored on a secured server. To ensure quality data collection, adolescents were assisted by a technician when completing questionnaires and a quality data control was computationally planned. The Board of Education and the adolescent's identification and socio-demographic data were crosschecked.

2.7.2. Outcomes

- **Anthropometry**

The anthropometric outcomes were: changes from T0 to T1 in BMI, BMI z-score [38], waist circumference, and waist-to-height ratio (WHtR) [39]; T1 BMI deviation from the T0 position curve; and overweight prevalence according to international cut-off values [20,40], WHtR > 0.5 cut-off and high waist circumference [21]. Combined BMI and waist circumference outcomes were considered. The main judgment criterion was change in BMI z-score.

- **Nutritional, attitudes and behaviors**

Food frequency questionnaire was especially designed in France [24] to assess the adherence to French guidelines [2] for fruits and vegetables, dairy products, starchy food, drinks, sugar foods, meat, and fish. The IPAQ assessed the frequency (days per week) and duration (minutes) of walking and moderate and vigorous physical activity during the previous 7 days. Physical activity level was defined as low, moderate or high according the IPAQ scoring guidelines [41]. Practicing at least 1 h of moderate to vigorous physical activity per day corresponded to French Program National Nutrition Santé (PNNS) recommendations for adolescents [42]. Practicing at least 1 h of moderate to vigorous physical activity per day with a minimum of 3 days of vigorous physical activity per week corresponds to WHO recommendations for adolescents [43]. For sitting time, the frequency (days per week) and duration (minutes) and context (school days, weekend, school, transportation, screen-viewing, other leisure-time) were assessed. A sedentary behavior was defined by the daily number of hours spent sitting.

- **Health**

The EAT-26 [26,27] explored 4 dimensions of dieting, bulimia/food preoccupation, oral control and overall eating disorder [31]. Scores were calculated and the cut-off values used are those recommended by the authors. The HAD scale [28,29] has acceptable psychometric properties in the general population [44]. The total score was the sum of the scores on the 14 items, and for each of the 2 subscales, the score was the sum of the scores for the respective 7 items. The Kidscreen [30] provided a global perceived health appreciation on a Likert scale ranging from 1 to 5 (excellent to bad) and a 10-item quality of life score. High score on the 0–100 scale indicates good quality of life. To facilitate interpretation, all health scores were normalized to a 0–100 scale.

- **Transition questions**

Outcomes transition questions provided the adolescents' perception of change and were answered on a Likert scale ranging from 1 to 5 (much better to much worse or yes a lot to not at all).

2.7.3. Sample size and smallest detectable difference

According to the characteristics of the participating high schools, approximately 3800 students attended grade 10 each academic year. Two waves of inclusion (2012/2013 and 2013/2014) were initially planned in each high school, corresponding to a total of 7600 expected students. According to the previous PRALIMAP study [8], 20% of adolescents were expected to meet the inclusion criteria and 10% were expected to refuse to participate. Under these conditions, we expected to be able to include 1250 adolescents over 2 years: 620 in the A.S group, 210 in the LA.S group and 420 in the LA.S.S group. Thus, the smallest detectable difference (SDD) was calculated with this sample size. The SDD for the BMI z-score (main judgment criterion) was calculated with a 5% type I error and 80% power and assuming a normal distribution of the 1-year change and a 0.44 common standard deviation (SD) [8]. For the first comparison of the primary objective (620 A.S vs 420 LA.S.S), we were able to detect an absolute true difference of 0.078 in mean BMI z-score change between the 2 groups. A 0.7 SD of change limits was chosen for every equivalent test (primary or secondary objectives). For the second comparison (620 A.S vs 210 LA.S), we were able to detect an absolute true difference of 0.099 in mean BMI z-score change between the 2 groups. For the first comparison (420 LA.S.S vs 210 LA.S), we were able to detect an absolute true difference of 0.104 in mean BMI z-score change between the 2 groups. Given the insufficient inclusion rate during the first academic year (2012–2013), to reach the expected sample size, adolescents attending grade 9 in the 13 committed middle schools were incorporated in the inclusion process and we added a third inclusion wave (2014–2015).

2.7.4. Statistical analysis

Baseline characteristics were described in a flow chart with different samples to determine the prevalence of overweight and obesity, search for a health social gradient, search for a possible selection bias due to parental refusal and described the initial characteristics of the PRALIMAP-INÈS study sample. The prevalence of overweight and obesity was determined among all adolescents attending grades 9 and 10 who were measured at the inclusion session. Baseline social

inequalities in health (social gradient) were investigated among eligible adolescents who completed the questionnaire and participated in the medical visit to confirm the hypothesis of important social inequalities in health and overweight among state-run school adolescents. Among adolescents proposed for inclusion, comparing included and not included adolescents (written parental refusal) aimed to seek for the existence of a selection bias related to parental ability to accept or refuse this kind of intervention. Continuous and discrete variables were described with mean ± SD and categorical variables with percentages. Statistical comparison involved use of Student *t*-test, Mann–Whitney *U* test, Wilcoxon signed ranks test for continuous or discrete variables and Pearson chi-square test for categorical variables as appropriate, and use of logistic or linear multivariate regression models using a stepwise variable selection method.

To respond to the purposes of PRALIMAP-INÈS, longitudinal analyses will compare the T1–T0 changes in the intervention groups 2 by 2 in accordance with intent-to-treat principle, regardless of adolescents' participation and degree of compliance with interventions. Adolescents' participation over the intervention and follow-up period will be described by a flow chart according to the CONSORT statement [45] and analyzed for possible selection bias especially along with social status.

The first comparison of the primary objective analysis (A.S vs LA.S.S) will consist of an equivalence test. For the second and third comparisons (A.S vs LA.S and LA.S vs LA.S.S), superiority analyses will involve mixed models accounting for the potential confounding factors identified in the previous steps and the hierarchical (possible school and wave random effects) and longitudinal nature of the data. An unstructured correlation matrix will be initially specified and the existence of a more appropriate specific correlation structure based on the data at hand will be. Additional analyses concerning changes in secondary outcomes (anthropometric, nutritional, attitudes and behaviors, health, transition questions) will involve models similar to those specified for the primary outcomes.

The dose of intervention adolescents received will be estimated by the process evaluation in terms of a score for participation quantity and quality and will be used in “In treatment approach” analyses.

Post-intervention T2–T1 analyses will involve the same model to investigate the sustainability of the intervention effects.

All statistical analyses involve use of SAS v9.3® (SAS Inst., Cary, NC, USA).

3. Inclusion data

3.1. Flow chart of the PRALIMAP- INÈS inclusion process

The flow chart of the inclusion process is in Fig. 2. A total of 10,279 adolescents were attending grades 9 and 10 in the 35 schools during the inclusion period. 8735 (85%) had available baseline weight and height measurement, and among them, 6393 completed the anthropometric measurement session with the waist assessment. Among the latter adolescents, 2282 (35.7%) were eligible for answering questionnaires and a medical visit. Of these, 2113 attended the medical visit and 1639 (77.5%) were proposed for inclusion; 220 were not included after the receipt of written parental refusal (inclusion rate 86.5%). A total of 1419 adolescents were definitively included, 1358 with weight excess (1117 according to BMI whatever the WC and 241 exclusively according to WC) and 61 only on health or demand criteria. The adolescents were distributed across the 3 groups of the PRALIMAP-INÈS trial as follows: 808 A.S, 415 LA.S.S and 196 LA.S. The proportion of parental refusal did not differ by intervention groups.

3.2. Baseline corpulence indicators among measured adolescents (n = 8735)

Indicators for state-run adolescents in the Vosges department were estimated among all adolescents with available measures (Table 2). Mean (SD) BMI and BMI z-scores were 21.1 (3.8) kg/m^2 and 0.13 (1.1), respectively, with an 18.4% overweight and obesity prevalence. The mean (SD) waist circumference was 74.7 (11.0) cm and 28.8% of adolescents had a high waist circumference according to the McCarthy classification. The mean (SD) WHtR was 0.45 (0.06) and 12.5% had a high WHtR. Corpulence indicators were higher for girls than boys (21.3 vs 20.9, $p < 0.0001$ for BMI; 0.15 vs 0.10, $p = 0.04$ for BMI z-score; 0.46 vs 0.44, $p < 0.0001$ for WHtR; 37.5% vs 20.2%, $p < 0.0001$ for high waist circumference). Boys and girls did not differ in overweight and obesity prevalence. Regarding the school type, all indicators were significantly higher for adolescents attending vocational high school than thus attending general high school or middle school.

3.3. Baseline social inequalities in health among eligible completers (n = 2113)

The FAS score was categorized in 5 classes: [0–2] highly less advantaged; [3,4] less advantaged, [5,6] intermediate, [7,8] advantaged and [9] highly advantaged (Table 3). Mean FAS score decreased consistently from 6.7 to 4.5 with the social and professional class of the family. The social gradient was striking for the benefits of advantaged adolescents. Among the 2113 adolescents, 72 (3.4%) were highly less advantaged and 133 (6.3%) highly advantaged, whereas the intermediate class was the most represented (n = 871; 41.2%). High social origins reflect better mastery of corpulence. The higher the social level, the lower the BMI (from 26.9 to 24.8 kg/m^2, $p < 0.0001$), BMI z-score (from 1.62 to 1.31, $p = 0.005$), WHtR (from 0.53 to 0.49, $p < 0.0001$) and obesity prevalence (from 26.4% to 6.8%, $p = 0.001$). The corpulence social gradient was consistent with other health characteristics: perceived general health ($p < 0.0001$), depression risk ($p < 0.0001$), quality of life ($p = 0.003$), fruits and vegetables consumption ($p < 0.0001$), sugary foods ($p = 0.01$) and proportion achieving physical activity guidelines ($p = 0.0003$ for French guidelines and $p < 0.0001$ for WHO guidelines). Conversely, high social class was associated with higher consumption alcohol ($p < 0.0001$). No social gradient was evidence for sitting time duration, health disorders and anxiety risk.

3.4. Written parental refusal among adolescents proposed for inclusion (n = 1639)

Among the 1639 adolescents proposed for inclusion, 220 were not included because of parental refusal (13.4% refusal rate) (Fig. 2). Written parental refusal was significantly associated, in multivariate regression, with age (odds ratio [OR] 0.8 [95% CI 0.7–0.9] for a one half-year increase), gender (girls: OR 2.1 [1.5–3.0]), school type (attending general high school: OR 1.5 [1.0–2.3]) and social and professional class of the family (Lower among farmers, craftsmen and workers compared to executives) (Table 4). Among weight indicators, only WHtR significantly predicted the written parental refusal (OR for 0.1 WHtR increase: 0.7 [0.5–0.9]). The probability of parental refusal was lower among adolescents with high eating disorder risks. Food consumption frequency, physical activity practice, sedentary behavior and other health indicators (smoking status, perceived general health and anxiety and depression risks) did not predict written parental refusal. Thus the participation was all the more so as the needs increased.

3.5. Baseline characteristics of included adolescents (n = 1419)

The 3 arms baseline characteristics are displayed in Table 5. Overall, 808 (49.3%) of adolescents were considered socially advantaged and included in the A.S group, 611 less advantaged adolescents were included either in the LA.S group (n = 196; 12%) or (n = 415; 25,3%) in the LA.S.S group. The mean (SD) age was 15.3 (0.7) in the A.S group, which was mostly composed of girls (54.1%), half-boarders (55.8%), general high schools attendees (49.9%),

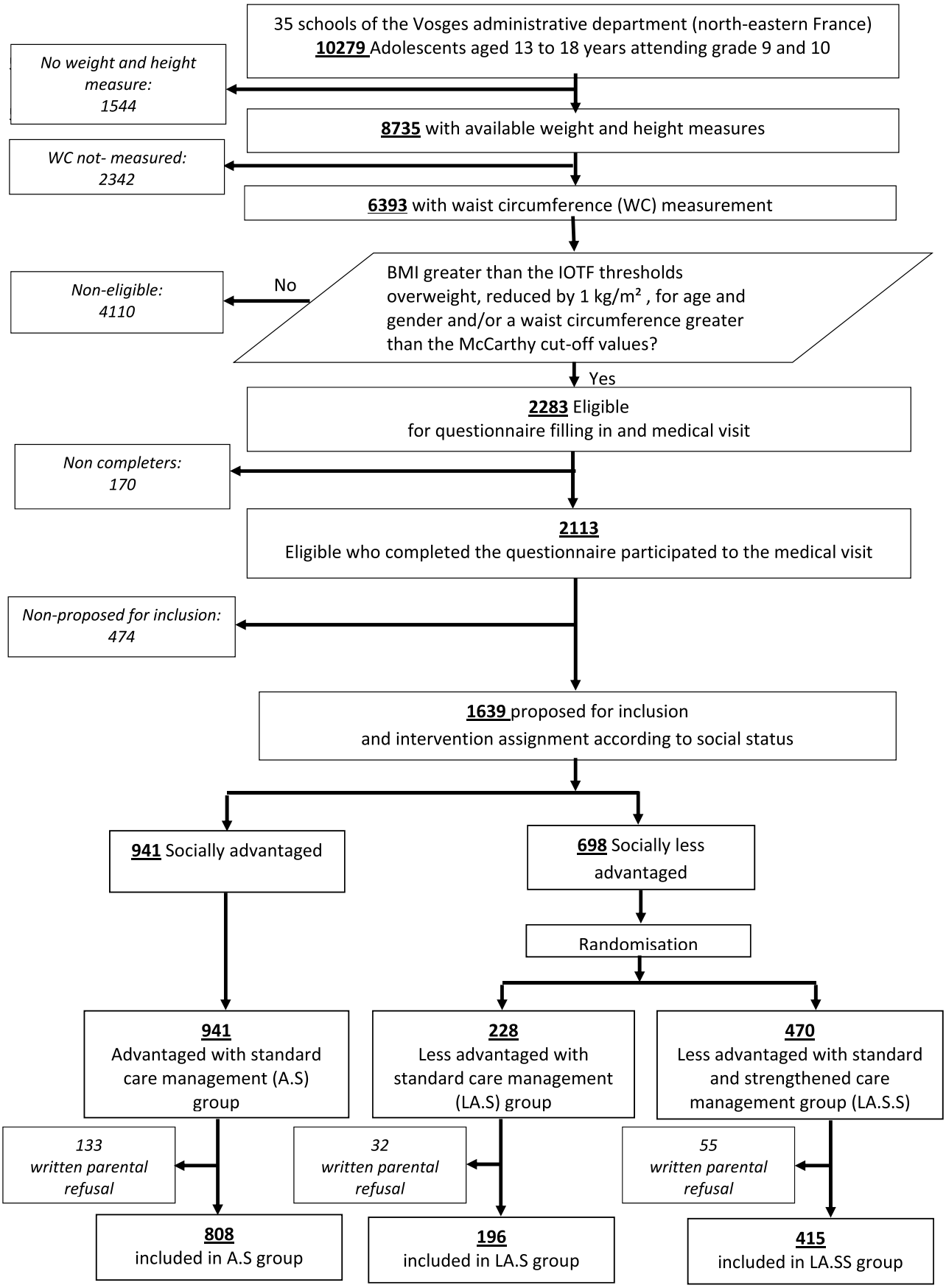

Fig. 2. Flowchart of the PRALIMAP-INÈS inclusion process.

Table 2
Baseline anthropometric characteristics among measured adolescents (N = 8, 735).[a]

	Measured adolescents	Boys	Girls	P*	Vocational high school	General high school	Middle school	P**
	N = 8735	4318 (49.4%)	4417 (50.6%)		2186 (25.0%)	5302 (60.7%)	1247 (14.3%)	
	Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	Mean (SD)	
Body mass index (kg/m^2)	21.09 (3.79)	20.86 (3.76)	21.33 (3.80)	< 0.0001	22.04 (4.41)	20.82 (3.43)	20.61 (3.82)	< 0.0001
BMI Z-score	0.13 (1.11)	0.10 (1.16)	0.15 (1.07)	0.04	0.31 (1.21)	0.05 (1.05)	0.13 (1.16)	< 0.0001
Weight status (IOTF classification)[b], (%)				0.29				< 0.0001
Thin	8.3	7.7	9.1		7.4	8.5	9.9	
Normal	73.2	74.0	72.5		67.3	76.4	70.1	
Overweight	13.9	13.8	14.0		17.8	11.8	15.6	
Obese	4.5	4.5	4.5		7.5	3.3	4.3	
Waist circumference (cm)	74.74 (10.6)	75.28 (10.88)	74.20 (10.29)	< 0.0001	77.66 (12.18)	74.48 (9.69)	71.55 (9.70)	< 0.0001
High waist circumference (McCarthy classification), (%)				< 0.0001				< 0.0001
Yes	28.8	20.2	37.5		38.1	26.5	22.9	
Waist-to-Height ratio (WHtR)[c]	0.45 (0.06)	0.44 (0.06)	0.46 (0.06)	< 0.0001	0.47 (0.07)	0.45 (0.06)	0.44 (0.06)	< 0.0001
High WHtR (> 0.5), (%)				< 0.0001				< 0.0001
Yes	12.5	10.3	14.7		19.9	9.4	12.7	

P-value of chi-square (for categorical variables) or *t*-test (continuous variables) comparison between boys and girls (*) and school type (**).
[a] Adolescents attending grads 9 or 10 who were measured (weight, height and waist circumference) during inclusion process.
[b] International Obesity Task Force.
[c] WHtR = waist circumference/height.

adolescents living with both parents (89.5%) and those perceiving their family income level as high (52.6%). The mean (SD) BMI was 26.3 (3.6) kg/m^2 for advantaged adolescents, 19.1% were obese (frequency of obesity among included adolescents) and 87.9% had a high waist circumference. They had a high level of fruits and vegetable consumption; 80% and 27.7% achieved the PNNS and the WHO physical activity guidelines, respectively; and 58.7% had a leisure-time sport practice. Among them, 28.1% were at high risk of eating disorders, 4% had a moderate or high risk of depression and 37.2% perceived their general health as very good or excellent. Compared to advantaged adolescents, less-advantaged adolescents were older (mean age 15.4 for LA.S and 15.5 for LA.S.S) and more often attended vocational high schools, lived in single-parent family and had parents who were mostly workers. They also exhibited more important weight excess (whatever indicators), a higher consumption of sugary foods and a lower physical activity level. Other health indicators were less favorable for less-advantaged than advantaged adolescents.

4. Discussion

The PRALIMAP-INÈS interventional research associated a large public health screening program involving more than 10,000 adolescents in 35 schools with a mixed prospective trial to determine the effectiveness of a strengthened-care management strategy to prevent overweight and obesity in socially less-advantaged adolescents. Although school-based interventions are not scarce [46–49], the reduction of social inequalities is not systematically addressed and when addressed, the usual approaches are observational studies describing inequalities [50] or targeted interventions implemented in low-income communities schools [48,51–53] or universal interventions with effects compared by socioeconomic status [54–56].

PRALIMAP-INÈS intended to address the effectiveness of the proportionate universalism strategy [57] applied at the individual level according to socioeconomic status. The final aim was to determine whether overweight interventions adapted to socioeconomic status could reduce or at least avoid the aggravation of social inequalities as compared with universalism prevention [58]. In this perspective, the best design appeared to be as follows:

- Easy collection of socioeconomic status near the adolescents themselves. For this purpose, the FAS was chosen for its shortness and validity demonstrated in the HBSC study [22]. For the purpose of randomization, the FAS score was dichotomized (cut-off = 5) for practical reasons The two groups were balanced, regarding their frequency in France [59] and a sufficient variability in the level of affluence was reached for offering strengthened care. Nevertheless, during the follow-up course, the interventions might be further adapted to the social status during the MDT meetings.

- The main comparison of advantaged adolescents receiving standard-care to less-advantaged adolescents receiving standard care plus strengthened-care management could only and obviously be quasi-experimental (the socioeconomic status cannot be changed by the researchers, the interventions and their implementation are controlled by the researchers) and had to be formulated as an equivalence comparison (doing as well).

- The experimental comparison (randomized assignment to standard or strengthened care within the less-advantaged group only) allowed for detecting the superiority of the strengthened activities among less-advantaged adolescents.

- Finally, a quasi-experimental comparison of advantaged and less-advantaged adolescents receiving the same standard universal intervention intended to confirm whether advantaged adolescents benefit more from interventions.

Initially scheduled over 2-year waves and only in high school (grade 10), the trial has been extended over 3 years and to middle school students (grade 9) because the first-year inclusion rate was lower than expected. The main reason was the disappointing height and weight declaration prerequisite leading to numerous overweight adolescents being missed. From the second year, the declaration was eliminated and all adolescents were invited to be measured. Additionally, middle schools were committed. The modification of the strategy of inclusion after the first year did not change the implementation of activities but allowed for achieving the sample size.

A good quality of the inclusion and follow-up data was warranted because of the unified procedure for collecting anthropometric, self-administered questionnaire and medical visit data. The computer-

Table 3
Social health inequalities according to FAS score among adolescents eligible for PRALIMAP-INES (N = 2, 113).[a]

	Highly less advantaged		Less advantaged		Intermediate		Advantaged		Highly advantaged		P[f]
	72 (3.4%)		397 (18.8%)		871 (41.2%)		640 (30.3%)		133 (6.3%)		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
BMI: Body mass index (kg/m^2)	26.94	4.90	26.19	4.55	25.57	3.68	25.30	3.54	24.79	3.26	< 0.0001
BMI Z-score	1.62	0.92	1.51	0.85	1.44	0.75	1.39	0.73	1.31	0.65	0.005
Obesity (IOTF classification)[b], (%)											0.001
Yes	26.4		16.9		18.0		14.7		6.8		
Waist circumference (cm)	88.37	12.04	86.51	11.99	85.31	10.12	84.91	10.06	82.94	9.80	**0.002**
High waist circumference (McCarthy classification), (%)											0.09
Yes	83.3		83.3		80.8		80.2		70.7		
Waist-to-Height ratio (WHtR)[c]	0.53	0.07	0.52	0.07	0.51	0.06	0.51	0.06	0.49	0.06	< **0.0001**
High WHtR (> 0.5), %											< **0.0001**
Yes	58.3		55.4		47.9		45.3		37.6		
High risk of eating disorders (EAT-26 scale), (%)											0.13
Yes	29.9		26.7		24.7		24.6		27.1		
Anxiety risk (HAD scale), (%)											0.80
No risk	62.5		58.7		59.8		61.4		58.6		
Low risk	16.7		22.9		21.0		18.8		21.8		
Moderate risk	18.1		13.4		14.6		15.0		13.5		
High risk	2.8		5.0		4.6		4.8		6.0		
Depression risk (HAD scale), (%)											< **0.0001**
No risk	73.6		78.6		83.1		86.1		87.2		
Low risk	15.3		14.6		12.4		10.9		6.8		
Moderate risk	11.1		6.3		4.1		2.7		6.0		
High risk	0.0		0.5		0.3		0.3		0.0		
Perceived general health (very good or excellent), (%)											< **0.0001**
Yes	26.8		33.8		37.1		42.7		47.0		
Quality of life (KIDSCREEN score)	46.39	11.22	47.59	11.71	48.03	11.85	49.64	12.18	50.52	12.67	**0.003**
Frequency of food consumption (number of times per week)											
Fruits and vegetables	18.02	11.62	21.34	11.08	22.86	11.36	24.57	11.73	27.31	11.74	< **0.0001**
Meats, eggs and fishes	12.79	7.50	13.11	6.42	12.86	6.07	13.04	5.95	13.49	6.41	0.94
Sugary foods	20.27	14.02	18.43	13.42	17.23	12.83	16.26	11.67	16.86	11.42	**0.01**
Dairy products	13.78	8.04	13.66	6.64	14.10	6.76	14.90	6.77	14.58	7.16	0.05
Starchy foods	11.95	6.41	11.23	6.16	10.74	6.02	10.50	5.67	11.26	5.77	0.07
Physical activity guidelines followed, (%)											
PNNS guidelines[d]	71.9		76.0		77.5		82.8		85.0		**0.0003**
WHO guidelines[e]	20.3		19.7		27.1		28.5		37.0		< **0.0001**
Leisure-time sport practice, (%)											< **0.0001**
Yes	47.2		49.0		53.3		60.3		72.2		
Sitting time duration (min/day)											
School days	646.47	376.92	700.45	342.81	698.78	350.10	697.79	335.05	704.35	314.90	0.60
Week-end	413.68	383.79	423.21	345.76	433.92	343.89	447.84	355.03	458.25	328.15	0.34
Smoking status, (%)											0.90
No smoker	61.1		62.5		65.0		61.0		61.7		
Experimenter	9.7		15.9		13.1		16.0		18.0		
Occasional smoker	6.9		5.8		4.8		6.1		4.5		
Daily smoker	22.2		15.9		17.1		16.9		15.8		
Frequency of alcohol consumption, (%)											< **0.0001**
Never	56.5		52.2		43.6		40.2		30.8		
Scarce consumption	33.3		36.4		40.7		39.2		52.3		
Monthly consumption	4.3		5.3		8.5		13.2		9.2		
Weekly consumption	5.8		5.0		6.9		7.5		6.2		
Daily consumption	0.0		1.1		0.2		0.0		1.5		

[a] Adolescents eligible who filled the questionnaire and participated to the medical visit Social classes: [0–2] Highly less advantaged; [3–4] less advantaged, [5–6] Intermediate, [7–8] Advantaged and [9] Highly advantaged.
[b] International Obesity Task Force.
[c] WHtR = waist circumference/height.
[d] At least one hours per day of moderate to vigorous PA.
[e] At least one per day of moderate to vigorous PA and at least 3 days of vigorous PA per week.
[f] P-value for linear trend test.

assisted questionnaire completion was easier than the paper version and also, the adolescents are assisted by a trained technician.

BMI and WC alone were insufficient to accurately diagnose overweight, especially among athletic adolescents, generally grouped in sport-curriculum classes, as shown by the 138 adolescents (29% of those not proposed for inclusion by the physician) of whom none were clinically diagnosed as overweight although fulfilling the BMI or WC criteria. Including a medical examination with BMI and WC measurements can help avoid misclassification and the proposition to participate in an inappropriate program.

PRALIMAP-INÈS corresponded to usual-care research according to the French ethical rules. Thus, after information dissemination, only a written parental refusal was the final non-inclusion criterion. Such usual-care research facilitated access to the program especially for less-advantaged adolescents because it did not require double parental consent. The non-requirement of parental consent associated with specific oral information given to LAS.S. adolescent parents may explain the non-significant difference in parental written refusal between

Table 4
Factors associated to written parental refusal among adolescents proposed for inclusion (N = 1639). Bivariate and multivariate logistic regression where the modelled probability is parental written refusal (n = 220).

	N	Written parental refusal		Bivariate regression			Multivariate regression[e]		
		n	%	Odds ratio	95% CI[d] lower upper	p	Odds ratio	95% CI[d] lower upper	p
SOCIODEMOGRAPHICS									
Age (By gone half-year)[f]	1639	220	13.4	0.78	0.70–0.87	< **0.0001**	0.79	0.7–0.9	**0.0029**
Gender						< **0.0001**			< **0.0001**
Boys	690	66	9.57	1			1		
Girls	949	154	16.2	1.83	1.35–2.49		2.14	1.51–3.02	
School type						< **0.0001**			**0.0215**
Vocational high school	586	46	7.85	1			1		
General high school	747	126	16.9	2.38	1.67–3.40		1.52	1.01–2.29	
Middle school	306	48	15.7	2.18	1.42–3.36		0.90	0.49–1.65	
School boarding status						**0.0187**			
Non-boarder	312	34	10.9	1					
Half-boarder	911	142	15.6	1.51	1.01–2.25				
Full boarder	392	42	10.7	0.98	0.61–1.58				
Family status						**0.0002**			
Two Parents	1389	202	14.5	1					
One parent	211	18	8.53	0.55	0.33–0.91				
Other	39	0	0.0	0.00	0.00-				
Social and professional class of the family						**0.0003**			**0.0214**
Executives	189	32	16.9	1			1		
Farmers, craftsmen	199	25	12.6	0.70	0.40–1.24		0.59	0.31–1.13	
Intermediate jobs	297	51	17.2	1.02	0.63–1.65		1.04	0.62–1.74	
Employees	381	64	16.8	0.99	0.62–1.58		1.19	0.72–1.97	
Workers	411	35	8.52	0.46	0.27–0.76		0.59	0.34–1.03	
Other	155	12	7.74	0.41	0.20–0.83		0.64	0.30–1.37	
Parents tertiary education						0.0716			
Both the two	173	25	14.5	1					
Only father	104	16	15.4	1.08	0.54–2.13				
Only mother	233	43	18.5	1.34	0.78–2.29				
No one	1129	136	12.0	0.81	0.51–1.28				
Perceived family income level						0.3251			
Low	151	15	9.93	1					
Average	745	98	13.2	1.37	0.77–2.44				
High	741	106	14.3	1.51	0.85–2.68				
FAS Score[f]	1639	220	13.4	1.06	0.98–1.15	0.1490			
PRALIMAP-INES intervention group						0.4232			
LA.S group[a]	228	32	14.0	1					
LA.S.S group[b]	470	55	11.7	0.81	0.51–1.30				
A.S group[c]	941	133	14.1	1.01	0.66–1.53				
ANTHROPOMETRICS									
BMI (kg/m²)[f]	1639	220	13.4	0.95	0.91–0.99	**0.0112**			
BMI z-score[f]	1639	220	13.4	0.79	0.65–0.97	**0.0246**			
Obesity						0.1940			
Yes	344	39	11.3	0.79	0.54–1.14				
Waist circumference(cm)[f]	1638	220	13.4	0.97	0.96–0.99	< **0.0001**			
High WC (McCarthy)						0.9832			
Normal	193	26	13.5	1					
High	1446	194	13.4	1.00	0.64–1.55				
Waist-to-height ratio[f]	1638	220	13.4	0.63	0.48–0.81	**0.0002**	0.71	0.54–0.95	**0.0202**
High waist-to-height ratio						**0.0340**			
No	674	105	15.6	1					
Yes	964	115	11.9	0.73	0.55–0.98				
NUTRITIONAL, ATTITUDES AND BEHAVIORS									
Frequency of food consumption (number of times per week)									
Fruits, vegetables	1636	220	13.4	1.00	0.99–1.01	0.9589			
Meat, eggs fishes	1637	220	13.4	0.98	0.96–1.00	0.1120			
Sugar drink and food	1638	220	13.4	0.99	0.97–1.00	**0.0273**			
Dairy products	1630	220	13.5	1.00	0.98–1.02	0.8692			
Starchy food	1630	219	13.4	0.99	0.97–1.02	0.5044			
French PA guidelines (1 h/day)						0.1381			
Yes	1205	170	14.1	1.32	0.91–1.93				
WHO PA guidelines (1 h/day with 3 days of vigorous PA)						0.7704			
Yes	377	49	13.0	0.95	0.67–1.34				
Leisure-time sport practice						0.6428			
No	758	105	13.9	1					
Yes	880	115	13.1	0.93	0.70–1.24				
Sitting time duration (min/day)									
School days	1556	208	13.4	1.00	1.00–1.00	0.4145			
Week-End	1537	209	13.6	1.00	1.00–1.00	**0.0379**			
HEALTH									

(continued on next page)

Table 4 *(continued)*

	N	Written parental refusal		Bivariate regression			Multivariate regression[e]			
		n	%	Odds ratio	95% CI[d]		p	Odds ratio	95% CI[d]		p
					lower	upper			lower	upper	
High risk of eating disorder (EAT26)							**0.0495**				**0.0295**
No	1113	163	14.6	1				1			
Yes	464	51	11.0	0.72	0.51–1.01			0.66	0.46–0.96		
Suspicion of anxious syndrom							0.8292				
No risk	945	131	13.9	1							
L ow risk	342	47	13.7	0.99	0.69–1.42						
Moderate risk	261	31	11.9	0.84	0.55–1.27						
High risk	91	11	12.1	0.85	0.44–1.65						
Suspicion of depression syndrom							**0.0468**				
No risk	1347	194	14.4	1							
Low risk	206	19	9.22	0.60	0.37–0.99						
Moderate risk	80	7	8.75	0.57	0.26–1.26						
High risk	6	0	0.0	0.00	0.00-						
Perceived general health (very good or excellent)							**0.0366**				
No	1073	131	12.2	1							
Yes	557	89	16.0	1.37	1.02–1.83						
Smoking during the previous 30 days							**0.0016**				
No smoker	1021	157	15.4	1							
Experimenter	244	26	10.7	0.66	0.42–1.02						
Occasional	87	15	17.2	1.15	0.64–2.05						
Current smoker	286	22	7.69	0.46	0.29–0.73						
Frequency of alcoholic beverage							0.1038				
Never	704	89	12.6	1							
1 or 2 times	627	94	15.0	1.22	0.89–1.67						
3–5 times	138	21	15.2	1.24	0.74–2.08						
6–9 times	96	7	7.29	0.54	0.24–1.21						
10 times or more	7	0	0.0	0.00	0.00-						

[a] Less advantaged with standard care management.
[b] Less advantaged with standard and strengthened care management.
[c] Advantaged with standard care management.
[d] CI: Confident interval.
[e] Only factors with a significant association at 0.2 in bivariate model were entered into multivariate model. Stepwise selection with significance level for entry into the model at 0.2 and with significance level for staying in the model at 0.05 was used. So, variables which don't appear in multivariate model don't answer to these selection criteria.
[f] Quantitative variables have no reference level. The odds-ratio expresses the risk variation for a unit increase of the variable.

the intervention groups. Moreover, the LAS.S. group showed a significantly higher written consent rate than the others (17.1% vs 10.2% (LA.S group) and 10.5% (A.S group), p = 0.002). Thus clear, oral and non-intrusive information appears to be a key to better inclusion acceptance in health promotion program directed to less-advantaged adolescents.

The prevalence of overweight and obesity was, as expected, stable and was even slightly lower than in the previous study [6] and in French national surveys [60] and European surveys [61]. During the last decades, the surveillance of child and adolescent overweight and major public health strategies to reduce the prevalence of overweight and obesity at every age [42] has resulted in a plateau (stability of adolescent overweight and obesity prevalence) during the 2000s in France, and the situation seems fairly favorable. However, this prevalence hides strong social inequalities in overweight and obesity [60] and related behaviors and health status among adolescents, which are consistent with the cultural and behavioral approach of health inequalities [62]. The difference in adolescents overweight prevalence between social classes reflects differences in health-related behaviors such as diet [63] and physical activity [64], and our findings agreed, except for sedentary behavior. Indeed, we did not find any social gradient of sedentary behavior, as was suggested by Meilke et al. [65]. However, the difference may be due to how the socioeconomic status of adolescents was assessed or because the PRALIMAP-INÈS trial concerned exclusively overweight or obese adolescents. Measuring health social gradient requires an optimal measure of social status with validated tools such as the FAS.

The proportionate universalism approach considers the people not only at the bottom of the health gradient, but also all over the gradient, thereby ensuring that the impact is proportionately greater at the bottom end of the gradient [57]. The PRALIMAP-INÈS trial was based on 4 of the 6 policy objectives required by Marmot et al. for reducing health inequalities [57]: give every child the best start in life; enable all children, young people and adults to maximize their capabilities and have control over their lives; ensure healthy standard of living for all; and strengthen the role and impact of preventing ill health.

One of the mechanisms by which the observed widening of health inequalities may operate in universal health interventions is social and cultural differences between health professionals delivering the intervention and the target audience. For adolescents, one way to counteract this social and cultural gap is by reaching adolescents of low socioeconomic status with similar peers in addition to interventions by health professionals, this was the basis of peer education [66,67].

Some adjustments were made to adapted activities (strengthened-care management) during the intervention. For example, the UNSS coupon, which was given to adolescents by their physician just after the medical visit during the first year, is then directly mailed to the adolescent's home. The sporting good was initially given as a 40-Euros voucher and then adolescents were asked to choose the good, which was brought to them by the trial group. All these adjustments aimed to enhance activity participation and were useful because they do not change the activity contents.

In line with recommendations [68] and in accordance with the previous PRALIMAP trial [6], the PRALMAP-INÈS trial was spread out over 1 year. A 1-year post-intervention evaluation was planned to investigate the continuing effect of the intervention, which aimed for medium term effectiveness. Choosing adolescents can ensure long-term effectiveness because the adolescence period corresponds to when the

Table 5
Socio-demographic, body size, behavior and health description of the 3 study arms. Formal statistical comparison (p) of advantaged and less advantaged groups.

	Less advantaged				Advantaged		p**
	LA.S group[a]		LA.S.S group[b]		A.S group[c]		
	N = 196 (13,8%)		N = 415 (29,2.3%)		N = 808 (49.3%)		
	Mean	SD	Mean	SD	Mean	SD	
Age (year)	15.4	0.7	15.5	0.8	15.3	0.7	**0.0007**
Gender, (%)							0.0902
Boys	37.2		43.4		45.9		
Girls	62.8		56.6		54.1		
School type, (%)							**< 0.0001**
Vocational high school	44.4		47.0		31.9		
General high school	38.8		34.2		49.9		
Middle school	16.8		18.8		18.2		
School boarding status, (%)							0.4912
Non-boarder	19.1		22.5		18.8		
Half-boarder	59.8		51.4		55.8		
Full boarder	21.1		26.2		25.4		
Family status, (%)							**< 0.0001**
Two-parents	77.0		75.4		89.5		
Single parent	19.9		20.0		8.8		
Other	3.1		4.6		1.7		
Social and professional class of the family, (%)							**< 0.0001**
Executives	8.2		4.4		15.3		
Farmers, craftsmen,	12.2		8.5		14.3		
Intermediate jobs	11.2		14.1		20.6		
Employees	19.4		23.5		22.6		
Workers	32.1		32.5		22.2		
Other	16.8		17.0		5.0		
Perceived family income level, (%)							**< 0.0001**
Low	15.3		15.0		5.4		
Average	52.0		49.8		42.0		
High	32.7		35.3		52.6		
FAS score	4.1	1.0	4.1	1.0	7.0	1.0	**< 0.0001**
BMI: Body mass index (kg/m^2)	26.9	4.3	26.9	4.4	26.3	3.6	**0.003**
BMI Z-score	1.7	0.8	1.7	0.8	1.6	0.7	0.06
Obesity (IOTF classification), (%)[d]							
Yes	25.5		24.3		19.1		< 0.0001
Waist circumference (cm)	88.4	10.6	89.0	12.2	87.1	10.5	**0.003**
High waist circumference (McCarthy classification), (%)							0.63
Yes	90.8		87.7		87.9		
Waist-to-height ratio	0.53	0.06	0.54	0.07	0.52	0.06	**< 0.0001**
High waist-to-height ratio							**0.0009**
Yes	64.8		65.0		56.1		
Frequency of food consumption (number of times per week)							
Fruits and vegetables	21.4	11.1	21.1	11.6	24.7	11.8	**< 0.0001**
Meats, eggs and fishes	13.5	6.2	12.7	6.6	13.1	6.2	0.85
Sugary foods	19.4	14.3	18.3	13.6	16.4	11.9	**0.009**
Dairy products	14.5	6.5	13.2	7.1	14.6	6.8	**0.0007**
Starchy foods	11.2	5.8	11.2	6.4	10.5	5.8	**0.03**
Physical activity guidelines followed, (%)							
PNNS guidelines[e]	70.8		76.3		80.0		**0.01**
WHO guidelines[f]	20.0		20.6		27.7		**0.002**
Leisure-time sport practice, (%)							**< 0.0001**
Yes	47.4		47.8		58.7		
Sitting time duration (min/day)							
School days	703.8	300.5	692.9	358.7	700.0	348.1	0.85
Week-end	420.8	312.5	457.7	373.4	440.5	360.8	0.80
High risk of eating disorders (EAT-26 scale), (%)							**0.04**
Yes	34.7		32.5		28.1		
Anxiety risk (HAD scale), (%)							0.75
No risk	55.6		57.3		57.8		
Low risk	19.4		23.4		19.8		
Moderate risk	18.9		14.2		16.6		
High risk	6.1		5.1		5.8		
Depression risk (HAD scale), (%)							**0.003**
No risk	80.1		75.7		84.4		
Low risk	12.8		16.6		11.5		
Moderate risk	7.1		6.7		3.8		
High risk	0.0		1.0		0.2		
Perceived general health (very good or excellent), (%)							**0.0002**
Yes	25.5		29.1		37.2		
Smoking status, (%)							0.11
No smoker	61.2		65.5		58.5		

(continued on next page)

Table 5 *(continued)*

	Less advantaged				Advantaged		p**
	LA.S group[a]		LA.S.S group[b]		A.S group[c]		
	N = 196 (13,8%)		N = 415 (29,2.3%)		N = 808 (49.3%)		
	Mean	SD	Mean	SD	Mean	SD	
Experimenter	15.8		12.0		17.0		
Occasional smoker	3.6		4.8		5.6		
Daily smoker	19.4		17.6		19.0		
Frequency of alcohol consumption, (%)							**0.0003**
Never	55.3		49.2		40.7		
Scarce consumption	34.7		38.2		40.7		
Monthly consumption	2.6		6.9		10.9		
Weekly consumption	5.8		5.6		7.2		
Daily consumption	1.6		0.0		0.5		

* P-value of chi-square (for categorical variables) or *t*-test (continuous variables) comparing advantaged and less advantaged adolescents.
[a] Less advantaged with standard care management.
[b] Less advantaged with standard and strengthened care management.
[c] Advantaged with standard care management.
[d] International Obesity Task Force.
[e] At least one hours per day of moderate to vigorous PA.
[f] At least one per day of moderate to vigorous PA and at least 3 days of vigorous PA per week.

future adult develops responsibility for health-related behaviors and attitudes that affect their future health [69]. Improving eating habits, physical activity and perceived health in adolescence is a major focus in overweight and obesity prevention because behaviors and habits initiated during this time are long-lasting [70]. The school setting is considered a facilitator for implementing prevention program and may be a primary setting for obesity prevention efforts [71].

The PRALIMAP-INÈS trial can be considered a pragmatic and complex intervention that needs effectiveness evaluation (outcomes change) and also an extensive and comprehensive process evaluation. The evaluation of processes involved in developing and implementing the intervention, the participation rate for all proposed activities, and the adherence and satisfaction with the intervention can help interpret observed relationships between the interventions and outcomes. Specific work is planned to provide an estimate of the dose of intervention by performing a per-protocol statistical analysis including the dose of each intervention received by each adolescent.

In conclusion, the PRALIMAP-INÈS trial, a large public health program, is conceptually constructed on the proportionate universalism approach to decrease weight excess and reduce the prevalence of overweight and obesity in adolescents. The data so far from this trial show an important social gradient in prevalence of overweight as well as nutritional behaviors (diet and physical activity) and perceived health in favor of socially advantaged adolescents. The PRALIMAP-INÈS results could help in proposing the most effective evidence-based strategy for reducing the social gradient in body weight as well as in nutritional behaviors, eating habits and perceived health in adolescents.

Authors' contributions

SB is the principal investigator for the PRALIMAP-INÈS trial. EL is interventions head manager. AO, KL, JL, EL, LM, LS, PB and SB are outcomes and process evaluation managers. AO, KL and SB are statistical managers. AO, KL and SB drafted the manuscript. The PRALIMAP-INÈS trial group have the power to make all strategic decision and assure the cooperation between investigator teams and between field actors and investigator teams. All authors read and approved the final manuscript. SB is the paper guarantor.

Competing interests

The authors declare that they have no competing interests.

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Appendix A. Supplementary data

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