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Effectiveness and cost-effectiveness of an online school-based programme to reduce eating disorder risk factors in preadolescents (PRETA): protocol for a cluster-randomised controlled trial

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ABSTRACT

Introduction Eating disorders are complex mental health conditions characterised by pathological behaviours related to food intake, often accompanied by a chronic obsession with weight control. Their prevalence is increasing, with an earlier onset and greater severity among young people. Universal prevention, through multicomponent strategies that tackle modifiable risk factors, has emerged as a promising tool. This paper reports the study protocol designed to assess the effectiveness and cost-effectiveness of the PRETA (Prevención de los Trastornos de la Alimentación) programme in reducing the risk of eating disorders and related modifiable risk factors among preadolescents in the school setting.

Methods and analysis The PRETA programme will be assessed by means of an open, community-based, multicentre, controlled trial using 1:1 matched-pairs cluster randomisation at the school level. Schools in Tenerife (Spain) will be assigned to the PRETA programme or a waitlist control group. Participants include 5th- or 6th-grade students (10–13 years old), their parents and teachers. The PRETA programme is a universal, school-based, multicomponent programme designed to reduce eating-disorder risk and modifiable risk factors. Its main component is an interactive online platform called e-PRETA, complemented by training sessions for families and teachers. e-PRETA includes nine 45-minute sessions addressing risk factors, such as dietary habits, beauty standards, media literacy, self-esteem, emotional regulation and social skills. A total of 1068 children from 12 schools will participate. The primary outcome will be the risk of developing eating disorders (Children's Eating Attitudes Test-26 item version). Secondary outcome measures are body dissatisfaction (Adapted Contour Drawing Rating Scale), eating disorder traits (Eating Disorder Inventory-2), internalisation of appearance ideals (Sociocultural Attitudes Towards Appearance Questionnaire-4) and self-esteem (Rosenberg Self-Esteem Scale). Outcomes will be assessed at baseline and postintervention (3 months). Additional baseline covariates such as electronic device use, parental feeding attitudes, physical activity, sleep duration and screen time will also be collected. Programme effectiveness will be analysed using generalised mixed models. Cost-effectiveness will be assessed by comparing the incremental costs associated with the implementation of the PRETA programme with its estimated effectiveness.

Ethics and dissemination Ethics approval has been obtained from the Ethics Committee for Research with Medicines at the University Hospital of the Canary Islands

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The PRETA (Prevención de los Trastornos de la Alimentación) programme tackles eating disorders from a universal prevention perspective, integrating psychological, social and cultural factors into a multicomponent intervention involving preadolescents and key figures in their lives, such as peers, teachers and family members.
⇒ The study uses a robust clinical controlled trial with a matched-pair cluster randomisation design, minimising contamination and optimising the evaluation of the intervention in a real-world school setting.
⇒ The waitlist design will ensure that, if the programme proves effective, all participants will have the opportunity to benefit from it.
⇒ The intervention for preadolescents, delivered via an online platform, enhances the standardisation, scalability, replicability and cost-effectiveness ratio of its implementation.
⇒ One potential limitation of the PRETA programme is that its implementation in other cultural contexts would require a process of contextualisation.

(CHUC_2021_78). Written informed consent will be obtained from the parents or legal guardians of all participants. Results will be disseminated through scientific publications and conferences.

Trial registration number NCT06792981.

INTRODUCTION

Eating disorders (EDs) are a group of highly complex mental health conditions characterised by a persistent disturbance in eating behaviours and/or eating-related behaviours and excessive worry about weight and shape control.[1] According to the DSM-5-TR,[2] these disorders include anorexia nervosa (AN), bulimia nervosa (BN), binge-eating disorder and other specified feeding or EDs. Additionally, mixed or partial ED presentations that do not meet the standard diagnostic criteria are referred to as unspecified feeding or eating disorders (UFED).

Although the exact aetiology of EDs is not fully understood, genetic, biological, psychological and social factors are acknowledged as key contributors. These factors include female sex,[3] adolescence,[3] body dissatisfaction,[4] high personal standards (self-imposed pressure to perform exceptionally well),[4] low self-esteem,[4] social hypersensitivity,[4] low frustration tolerance,[4] internalisation of societal appearance standards,[5] excessive appearance-based comparisons,[5] appearance-related teasing[6] and stressful or traumatic life events.[7]

Prevalence estimates of EDs in Spain vary due to methodological differences across studies, ranging from 0.14% to 0.9%, 0.41% to 2.9% and 2.76% to 5.3% for AN, BN and UFED, respectively.[3 6] There is a continuous increase in prevalence, especially during puberty when symptoms are more marked. In the Canary Islands, Spain, prevalence rates are similar.[8] Furthermore, a preliminary study using the Spanish Yale Food Addiction Scale for Children found that 20% of children aged 9–12 had scores indicative of a high degree of food addiction, which may be relevant to understanding disordered eating behaviours in this population.[9]

Epidemiological evidence further indicates that EDs most commonly emerge during adolescence, with a median age of onset of 15 years (IQR 14–16).[10] Moreover, childhood and adolescent onsets of AN (under 14 years and 14–17 years, respectively) have been associated with significantly greater severity and chronicity compared with later onsets.[11] Taken together, these findings emphasise the importance of considering younger populations in preventive efforts, as risk factors may emerge prior to the typical age of onset.

Following the COVID-19 pandemic, many countries reported an increase in ED diagnoses in both adult and paediatric populations,[12 13] along with earlier onset, more severe symptoms and a rise in atypical anorexia cases.[14 15] In the Canary Islands, a higher number of hospital admissions and an increase in self-harm and suicide attempts among paediatric patients with ED diagnoses have been observed compared with pre-pandemic levels.[16]

Evidence suggests that less than half of adults with AN or BN fully recover; another third may improve but remain symptomatic, while up to 20% experience chronic illness. Recent studies indicate that recovery is possible even after prolonged illness.[17] However, annual healthcare costs for patients with EDs are 48% higher than for the general population.[18] Adding to these challenges, up to 75% of individuals with EDs do not access treatment.[19] This highlights the need for preventive measures during preadolescence—a stage when risk profiles emerge[9]—to prevent chronic trajectories that negatively impact the lives and health of affected individuals and their families.[20]

At present, there are various promising preventive interventions which aim to tackle risk factors (or enhance protective factors) to prevent ED onset. Many focus on universal prevention.[21] This has the potential to help at-risk individuals and prevent new cases from developing.[21] Previous systematic reviews have revealed that universal prevention strategies,[22–27] including lifestyle-based interventions, media literacy programmes and multicomponent approaches addressing multiple risk factors, are effective in reducing some modifiable ED risk factors, such as body dissatisfaction,[22–24] media literacy,[22 24] weight and shape concerns[24 26] and negative affect.[24] Among these, multicomponent universal prevention programmes stand out for additional benefits, including reducing behaviours and symptoms associated with EDs, particularly in girls.[26] However, further research is needed to solidify their effectiveness and optimise implementation.[26] Building on this, a recent rapid review noted that most prevention and early intervention programmes have been evaluated in older adolescents and university students, well beyond the typical age of onset of EDs. These findings underline the importance of developing and testing preventive strategies at earlier developmental stages.[28]

One validated multicomponent universal prevention programme is the German Potsdam Prevention at Schools (POPS) programme.[29 30] Designed as an interactive primary prevention programme for schools, POPS excludes psychoeducation about EDs for students and instead leans into topics such as healthy eating, exercise, stress management, self-esteem, body acceptance and media-driven beauty ideals. The programme involves key stakeholders, including peers, teachers and families, with the latter receiving additional psychoeducational content about EDs.

Key aspects which enhance programme acceptability, equity and feasibility include the following[26]: (a) interactive, technology-mediated content through Information and Communication Technologies, that could increase the efficiency of these interventions, making them cost-effective and even cost-saving.[31 32] (b) Inclusion of boys, a traditionally under-represented group in such interventions, as most programmes focus on girls' specific risk factors, overlooking risks increasingly affecting boys.[26 33] (c) Delivery by trained teachers, ensuring ease of implementation.

This clinical trial protocol describes the planned trial of the PRETA programme (an acronym derived from the Spanish *Prevención de los Trastornos de la Alimentación*, meaning 'Prevention of Eating Disorders'), which assesses the effectiveness and cost-effectiveness of a universal, school-based programme to reduce eating-disorder risk and modifiable risk factors in preadolescents within the school context. The PRETA study adapts the POPS programme to the Spanish cultural environment, maintaining its comprehensive approach, content structure and inclusivity. It involves the following key stakeholders in ED prevention: preadolescents, parents and teachers. As an innovation, the preadolescent-targeted component is packaged into an online platform called e-PRETA,[34] which enables programme delivery with minimal teacher involvement. The programme also includes an informational guide for parents and specific training for teachers. The PRETA programme will be compared with the usual activities focused on promoting healthy lifestyles and emotional education conducted in schools.

In addition, in order to optimise benefits by targeting the primary components of preadolescents' interaction networks (peers, parents and teachers) and minimise contamination, the school is the unit of randomisation.

Our hypothesis is that the PRETA programme is effective in reducing ED risk among school-aged preadolescents and is cost-effective compared with standard care.

METHODS AND ANALYSIS

Study design

The PRETA study is an open, community-based, multicentre, clinical controlled trial, based on a superiority framework and conducted with a 1:1 matched-pair cluster randomisation. Participants are assigned to the PRETA programme intervention designed for preadolescents, parents and teachers or to a waitlist control group receiving standard health promotion activities (usual care). The study follows a waitlist-controlled design, meaning that the control group will gain access to the PRETA programme after the primary assessment period is completed. This approach allows for comparison with the natural course of outcomes in the absence of the intervention, while also ensuring that, if the programme proves effective, all participants will have the opportunity to benefit from it.

The clusters are the schools included in the study, with randomisation applied at the school level. All 5th- and 6th-grade levels (10–13 years old) in each school follow the condition to which their school is assigned. Study design details are reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement[35] and these are provided as online supplemental appendix 1. Full details of the WHO Trial Registration Data Set are also provided as online supplemental appendix 2.

Participants

The PRETA programme is implemented for preadolescents, parents and teachers.

Student inclusion criteria

1. Enrolled in the 5th or 6th grade of primary education.
2. Provision of informed consent by legal guardians and the teacher responsible for the activity.

Student exclusion criteria

Significant difficulties in understanding the programme's content (eg, not speaking or reading Spanish).

Parent inclusion criteria

1. Legal guardianship of a participating student.
2. Willingness and ability to participate in the PRETA programme activities.
3. Signing the informed consent form.

Teacher inclusion criteria

1. Teaching 5th or 6th grade in primary education.
2. Directly involved in the instruction of participating students.
3. Committing to implementing and supporting the programme's activities in the classroom.
4. Signing the informed consent form.

Cluster inclusion criteria

1. Schools with 5th- and 6th-grade students with access to computers or tablets with online connectivity.
2. Signed agreement to collaborate.

Setting and recruitment

12 schools in the Canary Islands, Spain, will be selected based on feasibility criteria, ensuring that they are located within 25 km of the research centre, and can be paired with a similar school in terms of size before randomisation. Meetings will be held with the management of each educational centre to request their collaboration and that of the teachers who meet the criteria. Teachers will also be asked to verify the inclusion and exclusion criteria of their students. Consent forms will be requested from teachers and parents (or legal guardians), both on their own behalf and on behalf of the minors. The initial contact with parents will be made by means of a letter. Students for whom consent is not obtained will not take part in the programme or its activities. The project will not prescribe specific alternative activities for these students. Instead, each school will determine the most appropriate option according to classroom dynamics and available resources. Schools will be advised to ensure that these decisions minimise the risk of stigmatisation for both participating and non-participating students.

The detailed schedule of enrolment, interventions and assessments is provided in online supplemental appendix 3.

Patient and public involvement

A co-creation model was used, involving a separate group of students to validate the e-PRETA platform. This development group reviewed the sessions, provided feedback on their preferences and opinions, and suggested adaptations to ensure their suitability.

Teachers will provide feedback and report their satisfaction levels at the end of each session.

Random assignment

The analysis units will be selected by means of a two-stage randomisation procedure. In the first stage, 12 educational centres (clusters) will be selected from the list of available schools based on the feasibility criteria described earlier. The selected schools will be invited to participate. If a school declines, its refusal will be recorded, and a similar school will be chosen as a replacement. Matched randomisation by six pairs of schools, based on the number of students in each school, will be used to allocate enrolled schools into one of two arms in a 1:1 randomisation ratio. A computer-generated random sequence will be used for randomisation, conducted by a research team member blinded to participant assessments and data analysis. All 5th- and 6th-grade classes from each participating school will be included to reinforce the integrity of the cluster-based design.

Concealment and blinding

The assignment to the intervention or waitlist control group will be revealed only after the recruitment process is complete and baseline measurements have been collected. Due to the nature of the intervention, blinding of participants after group assignment will not be feasible. However, data analysis will be blinded to the intervention assignment.

PRETA programme

Programme development

The PRETA programme's main component is an interactive online platform called e-PRETA, which delivers the intervention to students and is complemented by training activities for teachers and informational resources for parents.

Development of the PRETA programme content follows the structure of the POPS programme,[30] a universal school-based ED prevention programme for adolescents, which tackles body dissatisfaction and EDs from a co-educational and multi-component approach. The PRETA programme maintains the comprehensive approach of POPS by involving the key stakeholders in ED prevention: students, parents and teachers. However, two major modifications have been made to its design. First, the intervention for preadolescents is delivered via an online gaming platform that guides participants throughout the programme, allowing them to complete it autonomously. This shifts the role of teachers from being an active participant in the intervention's application to a more limited role as a classroom facilitator, thereby enhancing the programme's generalisability and standardisation. Second, the programme has been adapted to the sociocultural context of Spain, with its content validated by the target population.

The design of the programme activities is based on the following theoretical frameworks: the social-cognitive model,[36] the media literacy approach[25] and the tripartite influence model on body image and EDs.[37] These models emphasise the importance of addressing contextual factors (eg, family, friends, community), cultural influences and media that could contribute to both the internalisation of beauty ideals and social comparison, as well as the development of protective skills against these disorders, such as self-esteem, resilience and critical thinking in response to external influences.

The technical design of the e-PRETA platform, along with the gamification dynamics, is aligned to maximise the educational experience for primary school students. The interactive activities and gamification aspects are designed to capture students' interest and enhance their understanding by means of an engaging and immersive learning experience. The platform is based on WordPress technology, tailored with a specialised plug-in enabling the creation and management of courses segmented into levels. Each level includes interactive activities that facilitate knowledge acquisition, as well as review activities designed to reinforce learning and measure student progress. Furthermore, interactive activities integrate H5P, which offers key functionalities such as multimedia integration, interactive questions, creation of flexible quizzes in various formats, audiovisual activities, problem-solving tasks involving placement of elements, crossword puzzles and text areas for reinforcing concepts and reflections. The platform also includes a personalised H5P module allowing the selection and combination of elements across multiple stages. The platform allows researchers to track the progress of each student through different levels. The e-PRETA platform can be run on both tablets and personal computers in the classroom. If used in the classroom, it is recommended to have headphones available. Each child will have a user account, and only the data manager will know which identity the user corresponds to.

For validation, a co-creation model was used, recruiting groups of eight to ten students from the same school to assess each session. During 90-minute sessions, participants, accompanied by a project researcher and their teacher, reviewed the proposed intervention, provided feedback on their preferences and suggestions for adaptations, and expressed their level of satisfaction with the programme. Children's feedback was collected via semi-structured interviews, a qualitative method. Additionally, comments from teachers and researchers involved in the validation process were collected to identify potential difficulties in using the platform and assess the feasibility of implementing the programme in a school setting.

PRETA programme for preadolescents

The intervention for preadolescents is delivered via the e-PRETA platform. The content is structured into nine sessions, each lasting 45 min, to be conducted over consecutive weeks. Each week, the platform guides students through the activities that are to be performed in the classroom with minimal interaction from the teacher, as well as activities to be completed at home.

Each session addresses key topics related to the onset of EDs, including healthy eating habits and behaviours,[38 39] beauty standards and media literacy. In addition, activities aimed at improving different psychological skills or dimensions are incorporated, such as self-esteem, emotional regulation, problem-solving strategies, psychological flexibility and resilience. The programme also emphasises the enhancement of social skills, focusing on communication styles and the ability to distinguish between friendly teasing, mockery and systematic teasing among peers. For a detailed breakdown of the content of the sessions, refer to online supplemental table 1.

PRETA programme for parents

As part of the PRETA programme, families will receive specific materials. This resource includes an explanatory guide covering key aspects such as: the early identification of warning signs related to EDs, promotion of healthy lifestyle habits for the physical and emotional well-being of their children, information about the main risk and protective factors associated with EDs as well as guidance on how to detect early symptoms through changes in eating patterns, emotional state or social behaviour. It also includes practical tools to foster resilience, emotional regulation, problem-solving and self-esteem in children, which are further reinforced through recommendations on healthy communication and coping strategies. The materials provided to families also emphasise developing children's critical thinking (especially regarding beauty ideals), cultivating healthy communication styles within the family and addressing daily challenges such as anxiety, negative body image and peer pressure with emotional awareness and appropriate coping strategies.

PRETA programme for teachers

A 2-hour in-person session will be conducted by a general health psychologist specialising in ED prevention for the teachers responsible at each participating school to facilitate the implementation of the e-PRETA programme. During this session, they will be trained on how to use the platform and provided with tools to address the prevention of ED in the school environment. They will also receive online resources that will enable them to complement the in-person training.

The activity in schools will be monitored weekly by the researchers to improve adherence to the programme, and reminders will be sent to parents to ensure they access the information they have been provided with.

Standard care

The students in the waitlist control group will receive the usual health promotion activities at school, as established by the educational authority within the curricular programmes. Parents will not have access to the informational guide, and teachers will not participate in the specific training or have access to the programme's resources.

Outcome measures

Primary outcome measure

The primary outcome measure of the present study is the risk of developing an ED in preadolescents, assessed through the Children's Eating Attitudes Test (ChEAT-26) at baseline and again 3 months later (postintervention).[40]

ChEAT-26 is an adaptation of the Eating Attitudes Test (EAT-26) for children to facilitate question comprehension and prevent misinterpretation, and the Spanish version of the questionnaire will be used.[41] This consists of 26 items rated on a 6-option Likert scale. For each item (except for item 25, which is reverse-scored), the response indicating the highest symptomatology is 'always' (scored as 3), followed by 'almost always' (scored as 2) and 'often' (scored as 1). The remaining responses ('sometimes', 'almost never' and 'never') are scored as 0. The total score is obtained by summing all items, resulting in a range from 0 to 78 points. This instrument, using a modified correction (applying only 20 items and a cut-off of 17 points), has proven to be useful in detecting the risk of EDs in children aged 9 and older.[41] The 26-item version will be used in this project, although in addition, in an exploratory manner, the 20-item version will be analysed.

Secondary outcome measure

Secondary outcomes will be assessed at baseline and 3 months:

Adapted Contour Drawing Rating Scale (A-CDRS)

This is a visual scale designed to assess body image in children, consisting of seven contour figures for boys and girls, respectively.[42] The figures increase in size as the score increases, representing a range of body sizes. A body image discrepancy is calculated by subtracting the desired figure score from the perceived figure score. In order to enhance precision, the scale allows participants to mark their response using a ruler placed below the figures, enabling the use of decimal values by identifying up to nine intermediate points between two adjacent figures. Age-appropriate images adapted for children aged 10–13 years will be used. A difference of two or more points will be considered indicative of body dissatisfaction.[43]

Eating Disorder Inventory-2 (EDI-2)

This is an adapted version for children, validated in Spanish,[44] of the EDI-2.[45] This instrument consists of 91 items divided into 11 subscales: Drive for Thinness, Bulimia, Body Dissatisfaction, Ineffectiveness, Perfectionism, Interpersonal Distrust, Interoceptive Awareness, Maturity Fears, Asceticism, Impulse Regulation and Social

Insecurity. Only Drive for Thinness (7 items), Bulimia (7 items) and Body Dissatisfaction (9 items) will be used in the present study. The response scale is a 6-point Likert scale ranging from 0 (never) to 5 (always). The total score is obtained by summing all responses. A higher score indicates a greater presence of the trait.

Sociocultural Attitudes Towards Appearance Questionnaire-4 (SATAQ-4)

This 22-item self-report instrument is widely used to assess the internalisation of appearance ideals and perceived sociocultural pressures related to body image.[46] It consists of five subscales: Internalisation: Thin/Low Body Fat (items 3, 4, 5, 8, 9); Internalisation: Muscular/Athletic (items 1, 2, 6, 7, 10); Pressure from Family (items 11–14); Pressure from Peers (items 15–18); and Pressure from Media (items 19–22). Only the Internalisation scales (both Thin and Athletic) will be used. In addition, the pressure from media will also be used in this study. The items are rated on a 5-point Likert scale, ranging from 1 'completely disagree' to 5 'completely agree'. The total score is calculated by summing all items for each subscale; a higher score indicates greater internalisation and higher pressure, and the Spanish version of the questionnaire[47] will be used in this study.

Rosenberg Self-Esteem Scale (RSE)

This 10-item self-report scale assesses overall self-esteem.[48] The first five items are positively worded and are rated from 4 (strongly agree) to 1 (strongly disagree), while the last five items are negatively worded and are rated from 1 (strongly agree) to 4 (strongly disagree). The total score is obtained by summing all the items' responses. A score above 30 indicates high self-esteem, a score between 26 and 29 is considered medium self-esteem, and a score below 25 indicates low self-esteem. A validated Spanish version[49] will be used in this study.

Covariates and baseline measures

In addition, students will be asked about their use of electronic devices, distinguishing between school days and non-school days, as well as their preferences and time spent on social media.

Baseline characterisation measures for the students will be collected from their parents, including the students' weight and height (to calculate their body mass index), parental feeding attitudes,[50] physical activity, sleep duration and screen time. These measurements will be collected using an ad hoc survey.

For teachers, information on age, gender and years of experience will be collected. Furthermore, at the end of each session, teachers will complete a brief form to assess whether the activity was performed according to the protocol, their satisfaction with the session and any issues or comments that may have arisen.

Data on the execution of the intervention will also be collected, including the number of sessions attended by each teacher and student, the duration of each session, preparation time if applicable, and the number of students per classroom.

Finally, measurements of feasibility and acceptability will be collected from teachers and school management staff once the intervention is completed. Feedback on their satisfaction with participation in the programme will also be collected from parents.

Measurement procedures

The outcome measures for students and teachers will be collected at school in paper form. A research assistant, who is a licensed general health psychologist, will provide support with data collection and data entry.

Parents will be given the option to complete the information either online or on paper to improve response rates.

All the information will be stored in a protected Excel document that meets the required confidentiality criteria.

Statistical methods

A generalised mixed model will be used to analyse the effect of the PRETA programme. The dependent variable will be the postintervention measurement, adjusted for baseline measurement.

Level 1 variables will include individual-level student data: sex, academic year and baseline scores of the main outcome measures (ChEAT-26, A-CDRS, EDI-2, SATAQ-4, RSE), which will be included as covariates, respectively.

Level 2 variables will include school-level characteristics, specifically the intervention group assignment.

The model will include a fixed effect for the intervention group variable and a random intercept to account for clustering at the school level. Interactions between group and sex, as well as group and academic year, will be tested. If significant, stratified analyses will be conducted.

In order to address a potential floor effect in the scale, a subgroup analysis will be conducted to assess the effect of the intervention in students with baseline ChEAT-26 scores above 15.

The following will be considered in the sensitivity analysis:

1. The number of sessions attended by each class, or whether the nine sessions were completed, with a per-protocol analysis approach.
2. A modified correction of the ChEAT-26 using the validated 20-item correction.

If a class does not adhere to the protocol (fewer than five sessions), the reasons will be explored and reported, and results will be provided both including and excluding the data from non-adherent classes. No imputation of missing data is planned.

The same type of analysis will be applied to the secondary endpoints, using linear, logistic or Poisson regression depending on the characteristics of the dependent variables.

R will be used for data analysis,[51] and Microsoft Excel will be used for storing responses in paper form.[52]

Sample size calculation

It is estimated that with a power of at least 85%, a minimum of 12 schools and 1068 students (six schools and 534 students per treatment group) are required to detect an adjusted standardised difference of 0.30 points in the ChEAT-26 measure postintervention, taking into account the following criteria:

1. The standardised difference of 0.30 is based on a previous meta-analysis applied to multicomponent interventions.[26]
2. The calculation assumes that approximately 10% of the class children will not take part in the intervention, and 20% of the students will have missing data postintervention.
3. A multilevel mixed-effects model was considered, treating the school as a cluster-level (random effect) variable and the intervention as a fixed effect.
4. For sample size calculations, an intraclass correlation coefficient of 29% for schools and 41% for students (including school-level variance) was used.
5. The power for secondary analyses is approximately 50%.
6. The simr package[53] was used to simulate the data, a total of 10 000 simulations were used, and the script for generating simulations can be downloaded from Zenodo (https://shorturl.at/1T0yZ).

Cost-effectiveness analysis

A cost-effectiveness analysis will be performed from the healthcare system and the societal perspective. A short-term analysis (within trial) and a long-term analysis (remaining life expectancy of participants) will be developed. For the former, the primary endpoint of the study, the variable ChEAT-26, will be used as the effectiveness measurement, while costs will consist of the cost of implementing the PRETA programme. Cost-effectiveness will be calculated as the incremental cost of the PRETA programme divided by the incremental effectiveness to give the incremental cost-effectiveness ratio (ICER). Non-parametric methods for calculating CIs around the ICER based on bootstrapped estimates of the mean cost and effectiveness differences will be used. The long-term analysis will measure effectiveness in terms of quality-adjusted life years and will consider wider costs associated with the treatment and management of ED based on published literature and administrative data sources. A decision-analytical model taking the form of a Markov model will be used to synthesise the information and enable extrapolation over the expected lifetime of participants. Extensive deterministic and probabilistic sensitivity analyses will be undertaken.

Duration of fieldwork

Fieldwork is estimated to last 4 months. The first month will be dedicated to recruitment, while the following 3 months will focus on implementing the intervention and its evaluation.

Monitoring

Trial monitoring is the responsibility of a research team in charge of all quality assurance activities, assessing adherence to the trial protocol: timely work plan execution and comprehensiveness of data acquisition and data quality (databases have been designed to prevent the entry of invalid values for each variable).

ETHICS AND DISSEMINATION

Ethics approval has been obtained from the Ethics Committee for Research with Medicines at the University Hospital of the Canary Islands, with approval code CHUC_2021_78, dated 16 September 2021.

Written informed consent will be obtained from the parents or legal guardians of all student participants, as well as from the participating parents. Informed consent will be managed through each participating school using their standard communication channels with families and staff. The full set of consent forms is publicly available on Zenodo (https://zenodo.org/records/16964196) and is provided in online supplemental appendix 4.

Although the risk of unintended or iatrogenic effects cannot be completely ruled out (eg, increasing awareness of compensatory behaviours through assessment), procedures have been established to minimise this possibility. After the second assessment, the legal guardians of all participants will be provided with a personalised report including their child's scores, together with a recommendation to seek professional healthcare advice if problematic results are identified. This safeguard is intended to ensure early detection of potential concerns and to promote an ethically responsible approach to participant welfare.

The findings of this study will be actively disseminated in scientific publications and conference presentations, ensuring that insights are accessible to both academic and clinical communities.

Trial status

Recruitment for the trial began in March 2025 and was completed on 13 April 2025. Data collection was finalised on 20 June 2025. Data analysis is expected to be completed by January 2026, at which point the study will conclude.

DISCUSSION

This paper presents the detailed protocol for the PRETA study, a cluster-randomised clinical trial designed to assess the effectiveness and cost-effectiveness of a universal multi-component school-based programme aimed at reducing eating-disorder risk in preadolescents within the school context in the Canary Islands, Spain.

The PRETA programme is an adaptation of the German POPS programme to the Spanish cultural context, a programme that has shown its effectiveness in preventing EDs in Germany. Like POPS, PRETA adopts a multi-component approach that involves the following key

stakeholders in prevention: preadolescents, their parents and their teachers. The primary innovation of PRETA lies in its delivery format: an interactive online platform, e-PRETA, designed to facilitate standardised implementation in classrooms. By reducing the need for active teacher involvement, this format enhances scalability and helps lower implementation costs. Moreover, the use of gamification strategies enhances student engagement and promotes a better understanding of key concepts.

The cluster-randomised waitlist-controlled design is methodologically robust and well-suited to real-world educational settings. Randomisation at the school level minimises the risk of contamination across groups and ensures internal validity. Furthermore, the use of a waitlist control group ensures that all participants will have the opportunity to benefit from the programme if it proves effective.

The use of the 26-item version of the ChEAT-26 as the primary outcome measure, along with secondary outcome measures, will enable a comprehensive evaluation of the programme's effectiveness, including both the risk of EDs and modifiable risk factors. The statistical analysis plan, with mixed models and subgroup analyses, is designed to tackle the specific features of the cluster design.

The co-creation model for the development and validation of the intervention, along with the final assessment of participant satisfaction, is expected to help ensure its acceptability and feasibility within the school context.

Systematic reviews have shown that the use of universal interventions has proven effective in reducing ED risk factors, although their modest effects are likely attributed to a floor effect. Specifically, in the context of Spain, to the best of the authors' knowledge, no randomised controlled trial has assessed a universal prevention programme for EDs in this age group.

The need for the prevention of such disorders in preadolescents is crucial due to the increasing incidence and the vulnerability of this developmental stage, characterised by significant physical and emotional changes. Identifying and tackling the early signs of EDs, or even preventing them altogether, enables proactive intervention before the disorder is fully established, thus reducing the associated physical and mental deterioration. Furthermore, education on body image, self-esteem and healthy eating habits not only prevents EDs but also promotes a healthy lifestyle in general. Collaboration with families and schools is essential to create a supportive environment, reduce risk factors and promote the overall well-being of preadolescents.

Cost-effectiveness is especially relevant for assessing online interventions in the field of primary prevention, as the higher costs of these interventions correspond to the development of ICT applications. These interventions often reveal small effects that diminish over time, requiring widespread usage by thousands of people to attain a proper efficacy ratio. Currently, interventions must not only prove their effectiveness but also their cost-effectiveness to reduce uncertainty in decision-making regarding the earmarking of public health resources, in particular, and health policies in general.

However, this study is not free from limitations. First, the PRETA intervention cannot be blinded to preadolescents, parents or teachers. However, group allocation will remain concealed until the last participant has been recruited, in order to ensure the cooperation of teachers, preadolescents and parents.

Second, the PRETA intervention has been designed to prevent ED among preadolescents in the school context. However, the use of a universal approach in prevention programmes has been critically discussed due to the small effects that could be due to minimal effects experienced by many individuals or large effects experienced by high-risk individuals. In addition, preadolescents may vary in their level of motivation and interest in the topic, with those without signs or risk of ED potentially being less engaged with the content. To address this, the PRETA programme avoids explicitly focusing on EDs. Instead, it emphasises broader themes such as healthy eating habits, body image, media literacy and the promotion of protective factors such as problem-solving skills, stress management and self-esteem, making the content relevant and engaging for all students. Moreover, the interactive activities and gamification elements of the e-PRETA platform are designed to capture students' interest and enhance their comprehension by means of an immersive and engaging learning experience.

A further potential limitation is the generalisability of the programme. Its implementation in other cultural contexts would require a process of cultural adaptation and validation to ensure its relevance and acceptability in different populations.

In addition, although parents will be provided with educational materials through different channels, the authors will not include a measure to evaluate whether these resources will actually be read or used. Monitoring parental engagement will be challenging given the way the materials will be distributed, and this remains a limitation of the study.

Another limitation is that, although widely used in research on risk factors for EDs, the EDI-2 and SATAQ-4 have not been formally validated in children aged 10–12 years. Their inclusion was considered appropriate to allow comparability with previous studies, but findings related to these measures should be interpreted with caution.

Finally, there are concerns regarding the use of continuous measures of ED risk behaviours, such as the ChEAT-26 scale. However, this tool includes different cut-off points to identify participants meeting the criteria for clinical ED behaviour (although not formally diagnosed with an ED) and those at high risk, providing a comprehensive assessment for both screening and risk assessment purposes.

Despite these limitations, few previous studies have assessed not only the effectiveness but also the cost-effectiveness of universal interventions targeting all stakeholders involved in the prevention of EDs, using validated

interventions developed through co-creation processes and evaluated within a cluster randomised controlled design.

Taken together, these considerations underscore the importance of implementing early and comprehensive preventive strategies. EDs affect millions of people worldwide, and numerous studies have consistently reported that ED behaviours are associated with poorer health outcomes and increased healthcare costs. Therefore, it is crucial to implement effective prevention strategies to reduce the incidence of EDs and mitigate their impact on both individual well-being and healthcare systems. The PRETA study will assess whether a universal, school-based, online intervention aimed at promoting healthy eating habits, body image and media literacy, while fostering protective factors such as stress management and self-esteem, is effective and cost-effective in reducing ED risk among preadolescents.

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