Es tu juego: Decide Bien [It's Your Game: Keep It Real]. Cultural Adaptation, Validation, and Evaluation of the Programme for Promotion of Healthy Affective-Sexual Behaviours in Adolescents

V.3 (29/05/2025)

METHODS

Intervention

It's Your Game: Keep It Real (IYG) is an evidence-based hybrid educational game that combines face-to-face classroom sessions with digital modules delivered on school-based computers. The programme targets students of Grade 7 (aged 12 to 13 years) and Grade 8 (aged 13 to 14 years) in the United States of America - the equivalent in Spain is 1st (aged 12 to 13 years) and 2nd years (aged 13 to 14 years) of compulsory secondary education (ESO)- and is structured across two levels: Level I for Grade 7 students and Level II for Grade 8 students. Each level consists of twelve 45-minute sessions. Of these, eight are classroom-based and facilitated by a trained teacher through interactive methods such as group discussions and role-playing. The remaining four sessions in each level are computer-based and delivered via a virtual world interface that incorporates quizzes, animations, peer-led videos, and informational materials. For the virtual component, the use of the platform will be coordinated with the original developers of the programme. The adaptation may build on the platform *educa tailor*©, previously employed in the *Alerta Cannabis* project, which offers tailored guidance to users based on their individual needs (1).

IYG is grounded in three theoretical frameworks: Bandura's Social Learning Theory and Social Cognitive Theory (2), Social Influence Models (3,4) and the Theory of Triadic Influence by Flay and Petraitis (5). Social Learning Theory emphasises the interplay of personal cognition, behaviour, and environmental factors, with self-efficacy being central to behavioural change. Learning occurs through attention, focus, and motivation, with reinforcement playing a key role. Social Influence Models highlight how interpersonal interactions can shape beliefs, motivations, and behaviours. The Theory of Triadic Influence considers multiple levels of influence—cultural-environmental, contextual-situational, and intrapersonal—interacting to shape behaviour. With the aim of delaying the age of sexual intercourse and reducing sexual risk behaviours, IYG supports adolescents in identifying personal norms and boundaries regarding sexuality, recognising scenarios that may challenge those boundaries, and acquiring refusal skills to help maintain them. The programme also addresses a wide range of related topics, including the characteristics of healthy and unhealthy relationships, friendships, reproductive anatomy and physiology, the social, emotional, and physical consequences of sexual activity, teenage pregnancy and STIs, condom and contraceptive use, and communication skills (6).

Cultural Adaptation of the IYG Program

The cultural adaptation of the IYG programme in this study is guided by the findings of a recently published scoping review conducted by the research team (7). Based on this comprehensive review, the adaptation process employs three conceptual frameworks: the Ecological Validity Model, the Cultural Sensitivity Framework and IM-Adapt, which were previously used to adapt interventions in the field of sexual health (8–10). The Ecological Validity Model proposes eight dimensions to guide culturally relevant intervention adaptation: language, persons, metaphors, content, concepts, goals, methods, and context (8). The Cultural Sensitivity Framework distinguishes between two levels of adaptation: surface-level adaptations, which refer to visible and cultural adjustments e.g. names, images, language, and deep-level adaptations, which address underlying cultural values and meanings (9). The Intervention Mapping for Adaptation (IM-Adapt) comprises six steps: the assessment of needs, the search for existing interventions, the evaluation of cultural fit and the planning of adaptations, the implementation of these adaptations, the planning for delivery, and, finally, the planning for evaluation. This process ensures that the intervention retains its scientific foundation while being rigorously tailored to the characteristics and context of the target population. Finally, the recent review conducted by our colleagues identifies eleven steps that should be considered in the adaptation of evidence-based programmes (10).

The adaptation process uses a co-design approach and community-based participatory research, actively involves adolescents, families, teachers, primary care and school nurses, and other key stakeholders in the different phases of the review and refinement of the programme. This bidirectional collaboration ensures that the modifications faithfully reflect the realities, priorities, and cultural contexts of the participating communities, thereby guaranteeing the programme's relevance, acceptability, and long-term sustainability (11,12).

A mixed-methods approach guides the adaptation process, integrating qualitative and quantitative methodologies (13,14). This approach is optimal for achieving a culturally responsive and evidence-informed intervention. The qualitative component explores the experiences of adolescents, families, and facilitators, and provides insight into the programme's social validation, perceived usability, utility, and feasibility. The quantitative component assesses effectiveness in delaying sexual initiation and other key behavioural indicators through a community-based trial. The interaction of both components informs the utility and relevance of the adapted programme.

Bringing together all this information, the project unfolds in two phases. The first focuses on the cultural adaptation and validation of the programme content in three steps, and the second involves the pilot implementation and evaluation of the adapted intervention. Participating schools are selected from different areas of Granada (Andalusia) and Barcelona (Catalonia), considering accessibility and the establishment of a stakeholder network. The target population comprises students in the first and second years of compulsory secondary education (E.S.O.) in publicly funded secondary schools. Inclusion criteria specify that adolescents are aged 11–14 years and have access to a computer and internet at school. Students are excluded if they present linguistic, cognitive, or sensory difficulties that hinder completion of the intervention or questionnaires, or if their schools participate in another programme aimed at preventing affective–sexual risk behaviours.

Phase 1: Initial Cultural Adaptation and Pilot Usability Study for Social Validation

This phase comprises three sub-phases: the development of initial changes and the first draft of the programme, facilitator training, pilot testing, and refinement of the initial adaptation.

Phase 1. Stage 1. Initial changes and first draft of the programme.

The original materials are translated and back translated. Following the literature and COREQ criteria (15), Focus Groups (FGs) are conducted with adolescents to incorporate contextual and sociocultural factors related to sexual risk behaviours in Andalusia (Granada) and Catalonia (municipalities from Barcelona: Santa Coloma de Gramanet, Abrera and Badalona), and a first draft is developed by the research group in collaboration with the creators of the IYG programme and other relevant stakeholders from the intervention site, such as primary care nurses, school nurses, school teachers, or psychologists, who constitute the community advisory group. This initial adaptation draft of the programme incorporates the necessary modifications to tailor it to the context and characteristics of the target population, ensuring that the adaptations maintain fidelity to the original content while addressing the identified needs.

The FGs are composed of adolescents selected through theoretical and snowball sampling to ensure heterogeneity and gender balance, with the aim of identifying potential differences that may need to be considered in the adaptation of the intervention. A minimum of 10 FGs is expected, with the number adjusted according to data saturation. Each group consists of six to eight participants (16). Once schools agree to participate and parental and adolescent informed consent are obtained the FCs take place during school hours. A script is used based on the

principles of the IYG programme and the Ecological Validity, Cultural Sensitivity Models and IM-Adapt (8–10). To enhance the relevance and contextual appropriateness of the adapted intervention, the exploration of sexual behaviours and perceptions is integrated with the presentation of selected programme content. This approach enables participants to provide feedback that is grounded not only in general attitudes but also in direct responses to specific examples, activities, and messages from the intervention. FGs are also conducted with parents, recognising their central role in adolescent sexual health education and the sustainability of preventive programmes. Engaging parents helps to identify potential resistance, align the programme with family values and expectations, and foster active family involvement in supporting adolescents' healthy decision-making (17,18).

Data collected from the FGs are transcribed and subjected to content analysis, categorised into categories and subcategories. This process is carried out independently by two researchers to ensure methodological rigour. The analysis is conducted using version 14 of NVivo software.

Phase 1. Stage 2. Selection and training of facilitators.

The facilitators are the adolescents' teachers or nurses providing care in schools (19), depending on the local context, and are responsible for implementing the IYG programme in the educational centres and for interacting directly with the adolescents. Their training is based on the guidelines provided by the creators of IYG. They receive specific training on the IYG programme, its structure, objectives, and content over a period of two days.

Phase 1. Stage 3. Pilot usability study

A usability test is conducted based on previous adaptations (20,21), and the recommendations of Virzi and Nielsen (22). 50 students (25 per school level 1 and 2) from secondary schools in Andalusia and Catalonia participate.

The adapted draft of the IYG programme developed by Tortolero, Markham, Peskin and Shegog will be used. All 24 lessons are evaluated over six weeks (two lessons per week). Before the first lesson, a sociodemographic questionnaire is administered. After each lesson, a usability questionnaire is applied, including open-ended items (20,23). Likert-type scales are employed to assess the following elements: (1) Ease of use, with a scale ranging from "very easy", "somewhat easy", "somewhat difficult", "very difficult". (2) Credibility (accuracy of content), assessed with the options "correct", "incorrect", "don't know". (3) Comprehension (understanding of words and language used), motivational appeal (whether participants use IYG again and recommend it), and perceived impact (whether it helps them make healthy decisions about sexual relationships and friendships), assessed with the responses "yes", "no", "don't know". (4) Acceptability (pace of activities), assessed with "too fast", "just right", "too slow". The *Thinking Aloud* method is employed to identify usability or comprehension issues, and to detect points of friction or errors in the interface, instructions, or content (24).

Open-ended items provide complementary information on content quality, digital support, preferred and disliked elements, and suggestions for improvement. Fidelity is assessed through random observation of sessions by a researcher. Teachers and researchers complete monitoring forms for each session to evaluate quality, difficulties, positive effects, and student responses. These forms follow the FRAME model (Framework to Report Adaptation and Modifications–Expanded) (25), documenting modifications, their timing, context, actors, and rationale.

Data analysis considers descriptive parameters. Likert scales are transformed into dichotomous variables, and exact binomial probabilities are calculated for each item (23). This strategy evaluates response distributions and identifies significant patterns in usability, credibility, comprehension, motivational appeal, impact, and acceptability. Separate analyses are conducted by gender. Open-ended responses are categorised by thematic area.

Phase 2: Implementation, Evaluation, and Monitoring

This phase focuses on implementation, evaluation, and monitoring. The effectiveness of the programme is assessed through a community trial, concluding with dissemination of the results to support sustainability. The refined version is implemented in a randomised community trial with a wait-list control group (CG) and an intervention group (IG). A 24-month follow-up is conducted, corresponding to the full duration of implementation, as each programme level (first and second year of secondary school) lasts 12 months. The IG receives the IYG intervention, while the CG continues with usual education and both complete questionnaires at baseline and follow-ups. At the beginning, as in the usability testing, facilitators are trained by researchers over two days.

Cluster sampling is used. The sample size is calculated with the online GRANMO calculator (https://www.datarus.eu/aplicaciones/granmo/). Considering the onset of sexual intercourse as the primary outcome and accepting an alpha risk of 0.05 and a statistical power greater than 0.8 in a two-sided test to detect a difference between proportions of 0.2 in the unexposed group and 0.1 in the exposed group, three clusters per group are required, with 100 participants in each cluster (a total of six clusters and 600 participants). A very low cluster effect is assumed (intraclass correlation coefficient [ICC] = 0.001), along with a 30% loss rate. The *crtpwr.2prop* function from the *clusterPower* package in R is applied.

Assignment of the wait-list control group (CG) and intervention group (IG) is performed through simple randomisation. Each educational centre is assigned a number, and a random number generator determines its inclusion in either CG or IG, with approximately three schools per arm. Participants in the CG remain on a waiting list to receive the intervention once the project is completed This outcome is assessed through three separate questions addressing oral, vaginal, and anal sex.

Considering previous research on the IYG programme, school surveys are administered at different time points. Follow-up records are maintained for IG participants over the 24-month duration of the programme, covering both Level 1 and Level. Questionnaires are administered at four time points— baseline, at the end of the first and second school year of the intervention, and at the end of the following year —preferably in a computer-based format, with a paper version available if required. These questionnaires are administered by trained researchers and are carried out during school hours. Both the intervention and the questionnaires will be delivered in tutorial sessions or integrated into subjects related to life skills (6,20,21,23).

The primary outcome variable is the delay in initiation of sexual activity among participants who have not engaged in sexual intercourse at baseline (26,27). This outcome is assessed through three separate questions addressing oral, vaginal, and anal sex. In addition to the primary outcome, the study examines a range of secondary variables across several domains. For affective–sexual behaviours, these include late initiation of specific types of sexual activity; lifetime number of sexual partners; current sexual activity (defined as sexual intercourse within the past three

months); frequency of unprotected sex; number of partners within the past three months; number of partners without condom use in the same period; and condom use during the most recent sexual encounter.

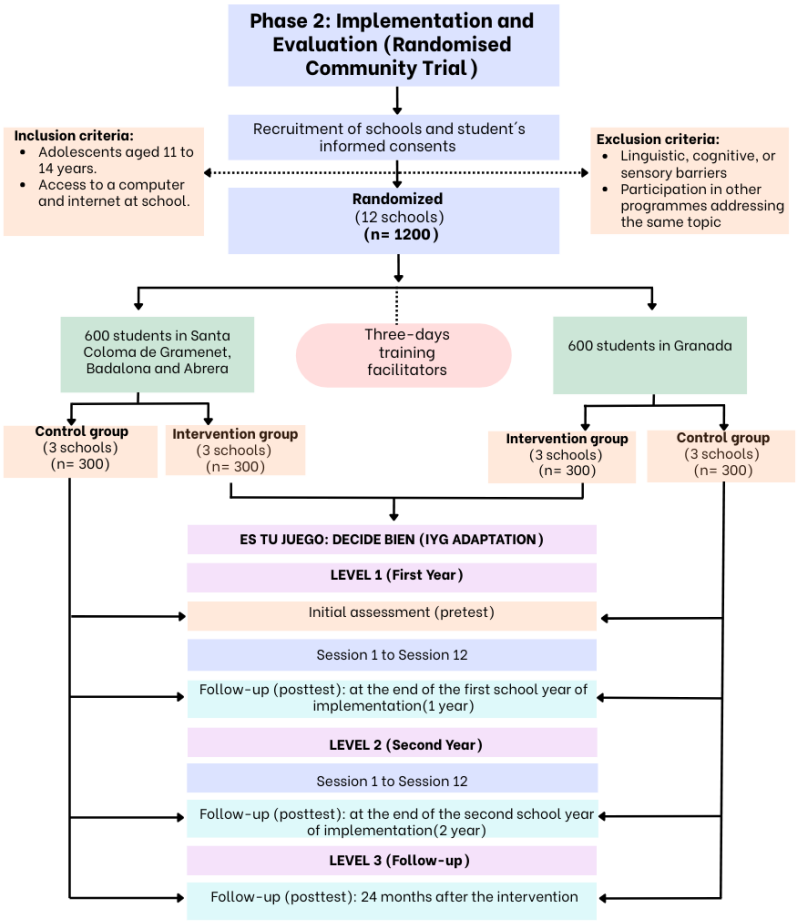
Psychosocial individual factors encompass knowledge about sexually transmitted infections (STIs) and condoms; beliefs about abstinence and condom use; perceptions of friends' attitudes towards abstinence; perceived peer norms related to sexual behaviour; self-efficacy in refusing sex and using condoms; intentions to engage in sexual activity, to remain abstinent, and to use condoms; reasons for not having sex; global character attributes; future orientation; and the number of personal boundaries established. Environmental factors focus on exposure to situations that may lead to sexual activity, as well as communication with parents or guardians about sex. Sociodemographic variables are collected, including city of residence, age, sex, gender identity, parents' or guardians' educational level, socioeconomic status, and family functioning, which are considered potential confounding factors.

To assess fidelity and quality of implementation, 12 sessions are randomly selected and observed over the 24-month period, including the first and last sessions. These observations involve researchers, external evaluators, and the promoting group. Facilitators complete checklists and a field diary after each session, using documentation provided by the programme creators. A data management plan is implemented to ensure appropriate use of collected data. The forms follow the FRAME model (Framework to Report Adaptation and Modifications–Expanded) (25), which documents modifications to the original programme, specifying when, where, by whom, and why each adaptation is made.

A descriptive analysis is carried out to examine differences between the intervention group and the wait-list control group using Student's *t*-test and the chi-square test. A multilevel multivariate analysis with generalised linear models assesses the effect of the programme on sexual initiation and other secondary outcomes. Sociodemographic variables are included as covariates. A significance level of $p < .05$ is applied. Effect sizes (Pearson's r and odds ratios) and 95% confidence intervals are calculated. Statistical analyses are performed using SPSS v31 and R 4.5.1. Differential effects by age, sex/gender identity, socioeconomic status, and family functioning are explored.

Below is the figure 1 illustrating the implementation and evaluation of the IYG programme through a cluster randomised community trial.

Figure 1. Flowchart – Phase 2: Implementation, Evaluation, and Monitoring


Phase 2: Implementation and Evaluation (Randomised Community Trial)
Recruitment of schools and student´s informed consents
Inclusion criteria:
Adolescents aged 11 to 14 years.
Access to a computer and internet at school.
Exclusion criteria:
Linguistic, cognitive, or sensory barriers
Participation in other programmes addressing the same topic
Randomized
(12 schools)
(n= 1200)
600 students in Santa Coloma de Gramenet, Badalona and Abrera
Three-days training facilitators
600 students in Granada
Control group
(3 schools)
(n= 300)
Intervention group
(3 schools)
(n= 300)
Intervention group
(3 schools)
(n= 300)
Control group
(3 schools)
(n= 300)
ES TU JUEGO: DECIDE BIEN (IYG ADAPTATION)
LEVEL 1 (First Year)
Initial assessment (pretest)
Session 1 to Session 12
Follow-up (posttest): at the end of the first school year of implementation(1 year)
LEVEL 2 (Second Year)
Session 1 to Session 12
Follow-up (posttest): at the end of the second school year of implementation(2 year)
LEVEL 3 (Follow-up)
Follow-up (posttest): 24 months after the intervention

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