


BMJ Open Serious game to promote socioemotional learning and mental health (*emoTIC*): a study protocol for randomised controlled trial

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ABSTRACT

Introduction The development of emotional competences may be a protective factor for mental health problems, promoting well-being at such a complex age as adolescence. Technologies may be used to carry out this empowerment because adolescents are attracted to them. The purpose of the study is to design a serious game based on the Mayer *et al*'s emotional intelligence ability model and analyse the effectiveness of the *emoTIC* programme to develop emotional competences, well-being, mental health, and personal strengths immediately after completion and at 12 months.

Methods and analysis The new version of *emoTIC* will be designed following the suggestions of the adolescents who participated in the pilot study and the results obtained from the statistical analysis. The participants will be 385 adolescents aged 11–16 years who will be randomly assigned to the control group and the experimental group. The experimental group will complete the *emoTIC* programme. The primary outcomes include emotional competences and subjective well-being. The secondary outcomes are self-esteem; general self-efficacy; personality; social and personal responsibility; school social climate; somatic complaints; depression, anxiety and stress symptoms; emotional and behavioural difficulties; suicidal behaviour; and subjective happiness. Data will be collected at three moments: baseline (T1), immediately post-intervention (T2) and 12-month follow-up (T3). The effectiveness of the programme will be analysed using different statistical packages.

Ethics and dissemination The study has been approved by the Ethics Commission of the University of Valencia (H152865096049), and the standards of the Declaration of Helsinki to collect the data will be followed. Results will be disseminated across the scientific community.

Trial registration number ClinicalTrials.gov Registry (NCT04414449).

Trial sponsor University of Valencia. Principal investigator: Inmaculada Montoya-Castilla.

INTRODUCTION

According to the World Health Organization (WHO), over 17 million adolescents, between 10 and 19 years, experience mental health problems such as depression, anxiety

Strengths and limitations of this study

- A strength of this project is to provide a serious game to promote emotional competences and well-being adapted to the needs of adolescents.
- The *emoTIC* programme will be available from any device (e.g., laptops, smartphones, tablets or computers) making it accessible to the majority of adolescents.
- The *emoTIC* programme is based on a solid theoretical model previously used in other programmes for the development of emotional competences which have shown positive outcomes.
- Family is not included in the intervention, which can be seen as a limitation of the programme.

or behavioural disorders¹; and suicide is the second leading cause of death among young people worldwide.^{2 3} Thus, a high number of adolescents suffer from emotional problems and will need pharmacological or psychological treatment. This is a public health problem whose prevention and treatment should be considered a priority.

The role of emotional intelligence

Intervening in emotions during adolescence is essential because it is a turning point in life with the development of new psychosocial and cognitive possibilities that have a neurobiological substrate.⁴ An adequate emotional development at this age would contribute to subjective well-being, fostering adjustment and preventing externalising and internalising problems,^{5 6} as well as improving social relationships in different contexts (peers, family, school, etc.).^{7 8} Emotional intelligence is a buffer against the negative effects of stress⁹ and it is considered a protective factor for suicidal behaviour.¹⁰

Empirical evidence suggests that emotional education programmes are effective and may

provide several benefits to adolescents.¹¹ For example, adolescents increased their intrapersonal and interpersonal emotional intelligence, and improve their stress management and general mood with a programme based on Bar-On's model¹²; and emotional programmes based on Mayer and Salovey's model improved adolescents' ability to perceive and manage emotions and satisfaction with life, while cyberaggression was reduced.⁸ Therefore, a web-based application such as *emoTIC*, which permits to follow a full intervention promoting emotional competences, may help to enhance adolescents' mental health.

The role of technology

One of the fundamental challenges with adolescents is to get them involved in the therapeutic process and motivated to carry out prevention and intervention programmes.¹³ Promoting learning and well-being through technologies could improve the motivation of adolescents to engage in socioemotional programmes.¹⁴ The use of digital interventions for promoting mental health and preventing mood disorders in adolescents has promising results.¹ In addition to technology, games can facilitate learning and promote motivation.¹⁵ In recent years, digital educational interventions have been implemented to prevent suicide¹⁶ or decrease depression and anxiety,¹⁷ but fewer focus on the development of emotional competences. Among the programmes designed to promote emotional competences, the following may be highlighted: the *MoodGYM* programme¹⁸ was designed to prevent symptoms of anxiety and depression in adolescents (12–17years); the *Think, Feel, Do* programme¹⁹ was developed to improve mental health and prevent emotional and behavioural problems in healthy adolescents (10–12years) and adolescents with emotional health problems (moderate anxiety or low mood) (10–16years); the *Bite Back* programme²⁰ was designed to improve adolescent well-being and mental health (12–18years); the *CopeSmart* programme^{21 22} was focused on developing mental health through emotional self-monitoring and the promotion of positive coping strategies (15–18years); the video game *Happy*²³ was designed to train emotional competences in situations both in everyday life and peer conflict at school, as well as to recognise and regulate emotions and learn adaptive and assertive responses (8–16years); the multimedia programme *Developing Emotional Intelligence*²⁴ and the video game *Spock*⁶ were focused on developing the four Mayer and Salovey's competences of emotional intelligence in adolescents (8–14years and 17–18years, respectively); the video game *Aislados*²⁵ was designed to improve the social competence and socioemotional well-being in adolescence (12–17years); finally, the online video game *REThink* is one of the most rigorously investigated video games aimed to promote emotional resilience, prevent mental health and develop emotional skills.^{26–29} *REThink* is based on positive preventive programmes derived from rational emotive behavioural therapy and education, and it is addressed to adolescents aged 10–16years. This kind of programmes showed effectiveness to promote

emotional competences and mental health. However, to our knowledge, there are few serious games focused on emotional competences based on Mayer and Salovey's model and other related variables implemented through mobile devices that have proven their effectiveness in healthy Spanish adolescents aged 11–16years, neither rigorously tested using a sample equally distributed by gender and a control group.

The current study

The development of emotional competences may be a protective factor for mental health problems, promoting adolescents' well-being. Technologies may be used in a positive way to carry out this empowerment because adolescents are used and attracted to them. Thus, the aims of the research are to design a serious game intended to prevent mental health problems and promote well-being in healthy Spanish adolescents between 11 and 16years old; and to analyse its effectiveness to develop emotional competences and personal strengths immediately after completion of the programme and up to 12 months. The study hypotheses are: (1) adolescents in the emotional ability programme will show an improvement in emotional competences, personal strengths and well-being, and less mental health difficulties than adolescents in the control group; and (2) improvements will be maintained up to 12 months.

METHODS AND ANALYSIS

Following the Standard Protocol Items: Recommendations for Interventional Trials statement,³⁰ the current study protocol describes the details of the study rationale, proposed methods, organisation and ethical considerations.

Study design and setting

A pilot study with a preliminary version of *emoTIC* was carried out in 2019, showing benefits in adolescents' self-esteem, hedonic balance and emotional symptoms.³¹ Participants informed that they have learnt emotional competences, social skills, and personal strengths; and suggested modifications to the duration, content, game mechanics, and design of the programme.³² These suggestions were incorporated into this new version of *emoTIC*. On the technical side, the programme has been transformed into a self-applicable tool and the graphics have been refined. On the content side, competences such as stress coping strategies, assertiveness or self-efficacy were added. This protocol describes an interventional quasi-experimental study, randomised clinical trial.

Participant timeline

The overall study was initiated in 2018 and the design of the platform was carried out during that year. In 2019, participants were recruited for a pilot study in order to test the platform and improve the programme. The main study is planned to take place from January 2021 until

Table 1 Time schedule for the study

	Study period*															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Phase I																
Enrolment and allocation	■															
Assessment T1	■	■														
Phase II																
<i>emoTIC</i> implementation†			■	■	■											
Phase III																
Assessment T2					■	■										
Preliminary data analysis						■	■	■								
Dissemination of preliminary results									■	■	■	■				
Assessment T3													■	■		
Final data analysis and dissemination													■	■	■	

T1=baseline; T2=post-treatment; T3=follow up.

*Presented in months.

†Only experimental group will complete *emoTIC* programme.

March 2022 (table 1). The main objectives of the phase I are the selection of targeted high schools, the request for informed consent and the initial assessment. Contact will be first with high school principals who have already manifested their interest and then will be extended to other centres in Spain. After the meetings with the principals, we will request informed consent from the families and adolescents who will participate in the programme. Prior to the implementation, adolescents will be requested to complete a battery of questionnaires. The main objective of the phase II is the implementation of the programme. Students will access the programme's website (www.emoticspace.com) and fulfil the activities of the programme in a maximum period of 3 months. Tutors will be involved to motivate the adolescents, as well as to monitor their progress. The main objective of the phase III is to analyse the effectiveness of the *emoTIC* programme. Once it has been completed, the variables assessed before the implementation will be reassessed. Also, a follow-up assessment will be carried out up to 12 months later. The principal investigator will make the final decision to terminate the trial.

Participants and eligibility criteria

Participants will be recruited from Spanish high schools. To participate in the project, adolescents between 11 and 16 years old will be requested to voluntarily accept to participate in the study. They and their legal guardians will have to sign the informed consent for participation (inclusion criteria). Exclusion criteria will be having a high rate of school absenteeism, not understanding the Spanish language and a diagnosis of psychological disorder.

Patient and public involvement

Participants were involved in the design of the research in the pilot study. Adolescents provided suggestions to improve the final version of the programme.

Interventions

The *emoTIC* programme aims to promote the four emotional competences of the emotional intelligence model of Mayer and Salovey.^{33 34} In addition, other competences and strengths proposed by Collaborative for Academic, Social, and Emotional Learning³⁵ are considered, intending to promote intrapersonal abilities (self-awareness and self-management), as well as interpersonal (social awareness and relationship skills) and cognitive (responsible decision-making) competences. The *emoTIC* programme consists of four modules, each one including eight activities and taking place in a different area of a planet called *E-MOOD*, following four general objectives: (1) emotional perception, valuing emotions and opening to the emotional world; (2) facilitation and emotional understanding; (3) stress management and conflict resolution; and (4) emotional regulation and self-motivation (table 2). The programme is available on a web-based platform that can be accessed from any device (e.g., laptops, smartphones, tablets or computers, among others). The mechanics of *emoTIC* as a serious game is a space adventure. The player has crashed on *E-MOOD* planet and the main objective of the game is to return to Earth, for which the player will have to obtain pieces to build a spaceship, as well as oxygen, fuel and crew members. The advance in the programme offers a positive reinforcement by obtaining the resources needed to return to Earth every time the player successfully passes an activity and moves to a new zone of the planet, as well as gaining points that can be exchanged for: (a) access to play minigames specifically designed with the same atmosphere as *emoTIC*

**Table 2** Activity contents and emotional competences

A	Activity content	Competences
1.1	The main characters of the planet ask adolescents to define emotions and test their emotional intelligence through a quiz.	► Basic concepts of emotions
1.2	The characters explain the emotion's dimensions and the user is asked to indicate the levels of intensity and liking of the emotions they are experiencing at the moment.	► Perceiving emotions* ► Self-awareness†
1.3	Human faces with different facial expressions are provided by the main characters and the adolescents are asked to identify the facial expressions corresponding to each emotion.	► Perceiving emotions*
1.4	The black stripes covering the faces gradually disappear and the adolescents are asked to identify the emotion as soon as possible.	► Perceiving emotions*
1.5	The adolescents focus on their feelings at that moment through a platform-guided audio. They are asked to draw and label their emotions.	► Perceiving emotions* ► Self-awareness†
1.6	The main characters provide drawn panels that represent emotional situations. The adolescents are asked to identify which emotion each person is feeling depending on the situation.	► Perceiving emotions* ► Self-awareness†
1.7	Three people speak in different languages and the adolescents are asked to identify the emotions they are expressing without understanding the content.	► Perceiving emotions* ► Self-awareness†
1.8	The main characters give clues to the adolescents to guess the hidden emotion. They offer information about valence, arousal, physical experience, similar emotions and situations in which the emotion is usually felt.	► Perceiving emotions*
2.1	The main characters propose a quiz to understand the function and meaning of emotions. Then, they provide situations to the adolescents and they are asked to identify how the emotion may help in each situation.	► Facilitating thought using emotions* ► Understanding emotions*
2.2	The characters encourage the adolescents to classify different emotions by categories: love, joy, sadness, fear, etc.	► Understanding emotions*
2.3	An emotional situation is presented. The adolescents may try to understand how the person feels based on the thoughts that the situation generates in the characters.	► Facilitating thought using emotions*
2.4	The adolescents indicate their perception of the arousal and hedonic valence levels in complex emotions. The main characters provide feedback and a definition of each emotion.	► Understanding emotions* ► Self-awareness†
2.5	The adolescents can discover the meaning of moral emotions with the help of the main characters.	► Facilitating thought using emotions* ► Understanding emotions*
2.6	The adolescents analyse a variety of emotional situations, trying to understand feelings and propose the 'intelligent optimist' thought. The main characters provide feedback to their performance.	► Facilitating thought using emotions* ► Self-awareness†
2.7	The adolescents reflect on their strengths and try to solve an emotional problem. The main characters provide information about each strength to help adolescents become aware of how to use them.	► Self-awareness† ► Self-management†
2.8	The main characters offer the adolescents their method for analysing emotional situations and they are asked to put it into practice.	► Facilitating thought using emotions* ► Understanding emotions* ► Self-management† ► Responsible decision-making†
3.1	The main characters ask the adolescents to indicate on their own bodies where they feel tension when they are stressed. They then explain the phases of stress and the adolescents are asked to classify different stressful situations.	► Psychoeducation about stress ► Identifying and classifying stressors
3.2	The main characters present different sounds (busy streets, sounds of nature...) and the adolescents are asked to determine whether they find them stressful or calming.	► Identifying stressful situations that impact on mood
3.3	The main characters teach the users strategies for coping with stress. Then, the characters describe their own stressful situations and the adolescents are asked to help them cope with those situations.	► Stress coping strategies ► Self-management†
3.4	The main characters explain and practise three relaxation techniques with the adolescents.	► Stress coping strategies ► Relaxation techniques ► Self-management†
3.5	The adolescents find themselves in a labyrinth and in order to escape, they are asked to confront alien characters, who express various emotions, and respond appropriately.	► Social awareness†
3.6	The main characters show the users several galactic portals with texts depicting social situations. Adolescents are asked to decide whether or not the behaviour depicted is respectful.	► Social awareness†

Continued

Table 2 Continued

A	Activity content	Competences
3.7	The adolescents are asked to identify people's emotions by taking into account their thoughts and interpretation of the situation. The main characters provide feedback.	<ul style="list-style-type: none"> ▶ Facilitating thought using emotions* ▶ Social awareness† ▶ Relationship skills†
3.8	The main characters explain what assertiveness is and how adolescents may use it in social situations.	<ul style="list-style-type: none"> ▶ Relationship skills†
4.1	The adolescents use a traffic light to indicate their agreement or disagreement with affirmations about emotional regulation. The main characters provide feedback.	<ul style="list-style-type: none"> ▶ Managing emotions* ▶ Self-management†
4.2	The adolescents choose the most appropriate emotional regulation strategies for each of the conflicting emotional situations they are asked to face.	<ul style="list-style-type: none"> ▶ Managing emotions* ▶ Self-management† ▶ Responsible decision-making†
4.3	The main characters ask the adolescents to imagine a difficult emotional situation and they are asked to label the emotion, think about the emotional regulation strategies they used and determine their usefulness.	<ul style="list-style-type: none"> ▶ Managing emotions* ▶ Responsible decision-making†
4.4	A situation depicting a human conflict is proposed by aliens. The adolescents answer the questions mimicking a conversation with a friend through text messages.	<ul style="list-style-type: none"> ▶ Managing emotions* ▶ Self-management† ▶ Relationship skills† ▶ Responsible decision-making†
4.5	The main characters challenge adolescents with conflicting situations to reflect on values and decision-making.	<ul style="list-style-type: none"> ▶ Self-awareness†
4.6	The adolescents make a recipe for happiness with five ingredients. Aliens ask them to whittle them down to just one.	<ul style="list-style-type: none"> ▶ Managing emotions* ▶ Self-management†
4.7	The main characters take a journey around the planet with the adolescents to reflect on what they have learnt from the challenges.	<ul style="list-style-type: none"> ▶ Self-awareness† ▶ Self-management†
4.8	The main characters confront the adolescents with challenges about their future and the goals they want to achieve. The adolescents are asked to reflect on the challenges and goals according to what they have learnt.	<ul style="list-style-type: none"> ▶ Self-awareness† ▶ Self-management† ▶ Responsible decision-making†

A=first digit corresponds to the module and the second digit corresponds to the activity.

*Competence of Mayer and Salovey's model.³³

†Basic competence proposed by CASEL.

CASEL, Collaborative for Academic, Social, and Emotional Learning.

which can be downloaded and played in mobile devices, and (b) funny elements to design and build a city on *E-MOOD*. The dynamics of the game are self-paced and self-instructive, facilitating the motivation and engagement of adolescents. Participants who do not complete 75% of the activities will be excluded from the study.

Sample size

According to the National Statistics Institute,³⁶ the population of adolescents (10–19 years) in Spain is 4 912 519. By choosing a 95% confidence level and a 5% margin of error, the representative sample size would be 385 participants. Participants will be randomly assigned to the control group and the experimental group using a computer-generated random numbers. The allocation sequence will be computer generated using a purpose-built application.

Outcomes

The assessment of adolescents will involve emotional, personal, social, psychopathological and well-being areas. All instruments will be completed by the participants in baseline (T1), post-treatment (T2) and follow-up (T3).

Primary outcomes

Emotional competences will be assessed by two instruments. First, the Spanish version of the Trait Meta-Mood Scale-24^{37 38} has 24 items divided into three factors (attention, clarity and emotional repair) with a 5-point Likert scale. The psychometric properties of the instrument were adequate in Spanish adolescent samples ($\alpha=0.83$ in the three dimensions).³⁹ Second, the Emotional Skills and Competence Questionnaire^{40 41} consists of 21 items divided into three scales (perception/understanding; labelling/expression; management/regulation), answered on a 6-point Likert scale. The questionnaire has shown good reliability in Spanish adolescent samples ($\alpha=(0.78$ to $0.91)$).⁴¹

Subjective well-being will be assessed by two indicators. First, the Satisfaction With Life Scale^{42 43} assesses the cognitive dimension of well-being, that is, how satisfied people are with their lives, and is composed of five items with a 5-point Likert scale. Its internal consistency with Spanish adolescents was adequate (McDonald's $\Omega=0.85$).⁴³ Second, the Scale of Positive and Negative Experiences^{44 45} assesses the emotional dimension of well-being

by the frequency of positive and negative feelings during the past 4 weeks. It consists of 12 items divided into two scales (positive and negative feelings) with a 7-point Likert scale, and it has shown good reliability in Spanish adolescent samples ($\alpha=(0.84 \text{ to } 0.92)$).⁴⁵

Secondary outcomes

Self-esteem. The Rosenberg Self-Esteem Scale⁴⁶ assesses the global attitude that adolescents have about themselves. It consists of 10 items scored with a 4-point Likert scale and has shown adequate psychometric properties with Spanish adolescents ($\alpha=0.87$).⁴⁷

General self-efficacy. General Self-Efficacy Scale^{48 49} assesses a stable feeling of personal competence to deal with a wide range of stressful situations. It is composed of 10 items answered on a 10-point Likert scale. The reliability in Spanish adolescent samples has shown adequate ($\alpha=0.89$).⁴⁹

Personality. The Mini-IPIP Scale positively worded Spanish version^{50 51} consists of 20 items answered on a 5-point scale and five dimensions: extraversion, agreeableness, conscientiousness, neuroticism and openness. The reliability of the factors in Spanish samples has shown adequate (composite reliability= $(0.87 \text{ to } 0.94)$).⁵⁰

Social and personal responsibility. The Spanish version of the Personal and Social Responsibility Questionnaire^{52 53} is composed of 14 items divided into two factors (social and personal responsibility), answered on a 6-point Likert scale, with adequate psychometric properties ($\alpha=(0.79 \text{ to } 0.80)$).⁵³

School social climate. School Social Climate Questionnaire^{54 55} consists of 14 items with a 5-point Likert scale grouped in two factors (social climate relative to the school and relative to the teaching staff). The reliability of the factors in Spanish adolescent population has shown adequate ($\alpha=(0.72 \text{ to } 0.77)$).⁵⁴

Somatic complaints. The Somatic Complaint List^{7 56} is comprised of 11 items, answered using a 3-point Likert scale, and has shown adequate psychometric properties ($\alpha=0.80$).⁵⁷

Depression, anxiety and stress. The Depression, Anxiety, and Stress Scale^{58 59} assesses the affective symptoms during the previous week and is composed of 21 items divided into three scales (depression, anxiety and stress) with a 4-point Likert scale. Previous studies indicated adequate psychometric properties in Spanish samples ($\alpha=(0.73 \text{ to } 0.81)$).⁶⁰

Emotional and behavioural difficulties. The Strengths and Difficulties Questionnaire^{61 62} is composed of 25 items distributed on five subscales (emotional symptoms, behaviour problems, peer problems, hyperactivity and prosocial behaviour) with a 3-point Likert scale and has adequate psychometric properties in Spanish adolescents ($\alpha=(0.72 \text{ to } 0.87)$).⁴⁷

Suicidal behaviour. The Adolescent Suicidal Behavior Assessment Scale⁶³ consists of 16 dichotomic items, 3 subscales (ideation, communication and act/planning) and a general factor. The reliability of the scale

was adequate in Spanish adolescent samples (Ω coefficient= $(0.84 \text{ to } 0.94)$).⁶³

Subjective happiness. The Spanish version of Subjective Happiness Scale^{64 65} is a 4-item Likert-type scale that requests the participant to self-rate or compare with others, and has shown an adequate reliability ($\alpha=0.81$).⁶⁴

Data analysis

Several statistical analyses will be used in order to determine the effectiveness of *emoTIC*. First, multivariate analysis of variance will be carried out to identify possible differences at T1 between the experimental group and the control group; and multivariate analysis of covariance will be performed to identify changes at T2, controlling for T1 scores (covariable). Second, the impact of the intervention programme will be analysed using multiple hierarchical regression analyses. The dependent variables will be the change between T1 and T2 in the outcome variables. Third, the reliable change index and X^2 tests will be calculated. Fourth, the moderating effects of demographic variables will be tested. The experimental condition will be the independent variable and the changes from T1 to T2 will be the dependent variables. Fifth, structural equation models will be explored in order to analyse complex relations between variables. Finally, qualitative comparative analysis (QCA) will be used in order to complete the results obtained by the linear models. The statistical analysis will be done by means of the statistical packages SPSS (V.23), the PROCESS Macro for SPSS, Mplus (V.6.12) and Fs/QCA (V.3.0). All data will be entered electronically. Participant files will be stored in a secure and accessible manner for a period of 10 years after completion of the study.

ETHICS AND DISSEMINATION

The study has been approved by the Ethics Commission of the University of Valencia (H152865096049) and will comply with the data protection law (Organic Law 15/1999 on the Protection of Personal Data). A purpose-built application will generate random codes for each student. Since adolescents under 18 years will participate, informed consent will be requested from them and their parents or legal guardians. The data will be analysed in order to determine the effectiveness of the programme and the results will be disseminated across the scientific community in different high-impact, peer-reviewed scientific journals. The results obtained in this study will be used for research and scientific publication purposes only, will be stored in databases and may be shared with other research groups, but will not be sold to third parties under any circumstances. Important protocol modifications will be reported to relevant parties (investigators, trial participants, trial registries, journals).

DISCUSSION

The present project aims to design a serious game called *emoTIC* and analyse its effectiveness to develop emotional competences, well-being, mental health and personal strengths. Triangulation of the data will be performed using multivariate analysis of variance, multiple regression analysis and reliable change index to determine the effectiveness of *emoTIC*. The anticipated results of this study imply to provide a motivational tool that positively impacts adolescents' mental health and well-being. Using technology in the implementation of socioemotional programmes could be the first step towards developing and promoting interest in emotional education in adolescents. Despite the strengths of the study, it will have limitations. First, family is not included in the intervention. Second, incidental school sampling could make it difficult to generalise the results of the programme.

CONCLUSION

Working on emotional competences and personal strengths may contribute to enhance mental health and well-being in adolescence. This project will provide relevant knowledge for both the theoretical and the practical fields. On a theoretical level, the data collected will help to expand knowledge in the field of emotional education, specifically in the development of effective programmes and the related variables that can improve emotional intelligence. On a practical level, it will offer a tool for learning emotional competences that may be applied in the academic, family or social environment.

Contributors UDIB—conceptualisation, methodology and writing (original draft). SP-Z—conceptualisation and writing (original draft). EM—conceptualisation and writing (review and editing). J-AG-G—funding acquisition, project administration and writing (review and editing). IM-C—funding acquisition, project administration and writing (review and editing).

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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