STUDY PROTOCOL:

Effects of positive surprises on momentary anxiety in youth at risk for social anxiety: a randomised controlled trial

Long Title of the Trial	Effects of affective training during social interactions on momentary anxiety in youth at risk for social anxiety: a randomised controlled trial
Short Title of the Trial	Social Training of Affective Responses (STAR)
Version and Date of Protocol	Version 1.0, 2025-11-20
Sponsor	University College London (UCL)
Funder(s)	Wellcome Trust
Trial Registration Number	ISRCTN.com: *pending*
Ethical Review	Ethical Review Authority approval number: 24867/001
Site	Department of Psychiatry, 1-19 Torrington Place
Principal Investigator	Prof Argyris Stringaris Division of Psychiatry, 149 Tottenham Ct Rd, London W1T BN, Department of Psychology and Language Sciences, Research Department of Clinical, Educational & Health Psychology, 26 Bedford Way, London, WC1H 0AP
Sponsor Representative	Prof Argyris Stringaris

Version history

Version number	Version date	Reason for Change
1.0	2025-11-20	First version of the study protocol.

SIGNATURE

Protocol version number: 1.0

Prof Argyris Stringaris, Principal Investigator

Date: _____

Signature: _____

1 TRIAL PERSONNEL

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2 SUMMARY

Title:	Effects of affective training during social interactions on momentary anxiety in youth at risk for social anxiety: a randomised controlled trial
Short title:	Social Training of Affective Response (STAR)
Objectives:	To evaluate the impact of the Social Training of Affective Response (STAR) intervention, a psychological task in the form of a video game which emulates social interactions and aims to modify individuals' expectations feared social situations, on momentary wellbeing in young people with social anxiety. The STAR intervention will be compared to an active control which looks identical in all respects to the STAR but provides random feedback that averages to 50%. The impact of the STAR intervention will be determined as the improvement it produces on momentary anxiety compared to a sham control.
Type of trial:	Parallel-group double-blind randomised controlled superiority trial

Rationale for the study:

This study seeks to test the effects on short-term wellbeing in young people with social anxiety of an intervention in the form of a psychological task that can be played as a video game either in person or online and which is designed to update expectations about feared social situations. Prior work indicates that the mood that young people with social anxiety feel in the moment can be improved if they experience positive outcomes and positive surprises in a social interaction (i.e. when the outcome of the interaction is better than they had expected). This work is based on ideas that come from the treatment of social anxiety using cognitive and behavioural therapy. We now seek to test this by comparing individuals who receive increasingly positive feedback with those who receive a sham intervention, that is, something that looks identical but with 'neutral' feedback.

Trial design and methods:

This is a parallel-group randomised controlled superiority trial for individuals with elevated levels of social anxiety.

A double blind, sham-controlled study of a computerised task that generates positive social feedback in a virtual social interaction (active group) compared to a task that is identical except for the generation of increasingly positive feedback (sham) of individuals recruited via: a) local communities (aged 18-25: tested online or in person), b) via online testing platforms such as Prolific (aged 18-25 and based in UK or US; tested online). This is an online platform commonly used for these research purposes. Participants from online platforms will be screened online immediately before the testing session.

All potential participants will be initially screened for eligibility.

Participants who are eligible and have consented will be randomised in a 1:1 ratio to one of two trial arms.

Participants will complete all outcome measures within no more than 90 minutes. Specifically they will complete them:

- at baseline (just before the start of the task)

- during the task (at intervals of 10-60 seconds)
- At the end of the two ‘main’ blocks
- At the end of a third, ‘challenge’ block

All measures will be self-reported within the technical platform.

Participant time in trial:	At least 50 minutes but no longer than 90 minutes
Total trial duration:	Approximately 24 months
Planned trial sites:	University College London, Division of Psychiatry
Sample:	A total of 550
Brief eligibility criteria:	Eligible participants will be aged 18-25 years and have elevated symptoms of social anxiety as identified using a threshold of 19 the Social Phobia Inventory (SPIN) (Connor, et al., 2000), and regular access to a computer connected to the Internet.
Statistical methodology and analysis:	The aim is to assess the efficacy of a Social Training of Affective Responses (STAR) intervention in improving the primary and secondary outcomes versus a sham intervention. The SAP will be finalised and approved prior to submitting this protocol and prior to randomisation. The programs and code to be used for statistical analyses will be prepared prior to unblinding as far as possible. A statistician will perform the primary analysis independently. We follow standard recommendations for the analysis of RCTs (Vickers, et al., 2001) using an ANCOVA formulation as described in detail in SAP.

3 INTRODUCTION

Both social anxiety and depression are very common and each is associated with great risk of suicide and overall impairment (Costello, et al., 1996; Merikangas, et al, 1995; Ballard, et al., 2019; Gallagher, et al., 2014). Young people are often affected by both social anxiety and depression, and this co-occurrence typically leads to worse outcomes in family life, education and interpersonal relationships than having each disorder on its own.

Cognitive therapy is the first line treatment recommended by the UK's National Institute of Clinical Excellence (NICE) in the UK (NICE, 2013). A recent meta analysis that shows large effect sizes for this treatment of social anxiety disorder against waitlist control [SMD = -1.62 (95% CI: -2.16, -1.08)], as well as active comparators, such as exposure therapy [SMD = -0.88 (95%CI: -1.24, - 0.52].

Having such large effect sizes is promising for work that aims at causal inference (Hill, 1965; Abelson, 1995). Understanding the mechanisms of treatment, opens for the possibility to maximize or further improve what is helpful about a treatment and remove unnecessary or even problematic components. Evidence from experimental testing has indicated that prediction error may be an important mechanism for treatment response, i.e., extinction (Craske, et al., 2008; 2014; Brown et al. 2017). This idea is also supported by experiments done on patients with obsessive compulsive disorder (Guzick, et al., 2020). However, to the best of our knowledge, no direct causal manipulation of prediction errors in therapy has yet been published.

Prediction errors are a fundamental mechanism through which organisms learn about the state of the world and their position within it (Schultz, et al., 2000; Corlett, et al., 2022). In simple terms, prediction error is essentially a measure of how well a model, or an individual's expectations match real-world outcomes. Over the last years, prediction errors have become an area of intense interest in psychotherapy research. In this context, CBT can be seen as a form of error-based learning since a core strategy is to create so-called behaviour experiments to challenge erroneous beliefs and behavioural patterns.

Whilst prediction error can occur in any domain (e.g., prediction errors in perception, reward or affect), belief-based prediction errors have been central to cognitive therapies of anxiety disorders for a long time. Indeed, the concept of belief disconfirmation (Salkovskis, et al., 2007; Clark, et al., 1995; 1999)—where a patient is presented with situations that maximise the possibility that they will disconfirm a negative belief—is akin to the notion of prediction error in the belief domain. In social anxiety disorder treatment, a prediction error occurs when the outcome of a social interaction is better than expected, that is the beliefs that the person initially held about the outcome of the interaction are disconfirmed.

In previous work (Bagdades, Biria et al. 2025), we experimentally demonstrated that both social prediction errors and social feedback play a crucial role in shaping momentary anxiety and mood. Importantly, individuals with elevated social anxiety and depression symptoms exhibited heightened affective sensitivity—their momentary affect was more responsive to social feedback. This sensitivity may represent both a potential risk marker and an

intervention target. In the current intervention, we test the latter by systematically presenting increasingly positive social feedback, therefore inducing sequential positive social surprises.

To test this we will create a scalable set up for testing the real-world relevance of these manipulations. The set up will emulate as closely as possible the social interaction that is used in so-called behavioural experiments in the treatment of social anxiety disorder. The scalability of the set up is highly important, that is it must be possible to reach many individuals with it. This is key because typically large sample sizes are required for robust inferences in mental health research, but also because any potential intervention may reach more people if it can be done online.

The purpose is to test whether the suggested manipulations of social feedback have an impact on how young people feel during social interactions in an ecologically valid set up. To demonstrate that the hypothesised active ingredient has relevance beyond the laboratory we will test it in a simulated real-world setting. Participants will complete a task involving simulated social interactions. Within this task, they will be randomised to receive either increasingly positive (and therefore surprising) social feedback (intervention arm) or neutral social feedback (control arm). Both groups will then complete a third block of the task in which they receive negative feedback, allowing us to test their affective response to it. The primary outcome will be anxiety levels at the end of the main task (i.e., after the first two blocks). Secondary outcomes will include: (1) momentary mood at the end of the main task; and (2) affective resilience to negative feedback — operationalised as momentary mood and anxiety measured after the negative feedback section of the third block (but before the positive feedback that ends the task). This second secondary outcome thereby assesses whether any effect on the primary outcome is maintained when participants are subsequently exposed to a social threat.

4 OBJECTIVES

Primary:

1. To evaluate the impact of the Social Training of Affective Responses (STAR) Trial, a psychological task in the form of a video game which emulates social interactions and which is designed to generate positive social surprises (prediction errors), on momentary wellbeing in young people with social anxiety. The STAR trial will be compared to an active control which looks identical in all respects to the STAR trial but provides random (and overall neutral) feedback. The impact of the STAR trial will be determined as the improvement it produces on momentary anxiety at the end of the two ‘main’ blocks.

Secondary:

1. To assess the difference in momentary mood at the end of the two ‘main’ blocks.
2. To assess the duration of effect on momentary mood and anxiety following a third 'challenge' block, in which participants receive sequential negative feedback (15 trials) before ending on 5 positive trials.

5 PROJECT DESCRIPTION

5.1 DESIGN

This is a double-blind parallel-group randomised controlled superiority trial for individuals with elevated levels of social anxiety.

Participants entering the study will be randomized to either the active or closely matched control intervention condition in a 1:1 ratio via a random-number generation procedure embedded in the task code. All participants will complete a baseline assessment, followed by the intervention (active or control). All procedures will take place over a single session (around 1 hour duration but no longer than 90 minutes).

To evaluate the impact of the Social Training of Affective Responses (STAR) trial — a psychological task in the form of a video game that emulates social interactions in which feedback becomes increasingly positive — on momentary wellbeing in young people with social anxiety. This trajectory is designed to generate positive social surprises (prediction errors) and to mirror a common real-world social dynamic, whereby social reward increases the longer one remains in an interaction (e.g. meeting a stranger who initially feels neutral but becomes progressively more engaged over time). The STAR trial will be compared to an active control identical in appearance but providing random feedback.

The impact of the STAR trial will be determined as the improvement it produces on momentary anxiety (primary outcome), momentary mood and affective resilience to negative feedback (secondary outcomes).

5.2 STUDY SITE

The study is conducted at the University College London, Department of Clinical, Educational and Health Psychology and online . More specifically, the study will take place:

1) Either online or in person, at the Torrington place 1-19 for 18-25 year olds recruited from the local communities.

3) Online testing platforms such as Testable Minds, CloudResearch, Prolific, Pavlovia for 18-25 year olds.

5.3 POWER ANALYSIS

Please refer to section 8.1 for a detailed explanation of the analytical approach. Using the ANOVA formulation in 8.1.1, we estimated the required using the following standard

formula:

$$n = \frac{2(z_{1-\alpha/2} + z_{1-\beta})^2(1-\rho^2)}{\delta^2}$$

Where α is the probability of Type I error, β is the probability of Type II error, ρ is the correlation of the instrument between baseline and outcome, and δ is the difference between the two groups (effect) powered for.

Setting $\alpha = 0.05$, $\beta = 0.1$ (90% power), and $\rho = 0.12$ (based on our pilot data), for detecting a 0.3 standard deviation difference, in momentary anxiety at the end of the second block (primary outcome) and adjusting for 20% attrition rate, we need a sample size of:

$$n_{infl} = \frac{n}{0.8} = 578$$

5.4 INCLUSION CRITERIA

1. Elevated symptoms of Social Anxiety Disorder as assessed by the age-appropriate Social Phobia Inventory (SPIN), defined as scoring above 19, which is the suggested cut off for social anxiety.

2. Age between 18 and 25 (inclusive)

    a) Confirmed by the participant during screening

3. Regular access to a computer connected to the Internet

    a) Confirmed by the participant during screening

4. Residence/Current location in the UK or US

5. For online recruitment sites like prolific we will:

a) Include a prolific approval rate of 95% as an inclusion criterion. This refers to the percentage participant's previous prolific jobs that have been approved.
b) Require participants to have previously completed at least 10 jobs on prolific.
c) Include 2 attention checks. If participants fail both, they are excluded from the study.

Individuals are not eligible if they:

1. Don't speak sufficient English to complete questionnaires and engage in the English language-based task.

    a) For online participants, this will be achieved by exclusively inviting participants from English speaking countries, specifically US and UK, who have indicated they are fluent in English.
    b) For local community participants, we will be recruiting through UCL which is an English speaking institution.

2. Have sensory or other deficits that preclude them from processing the computerized tasks

    a) Confirmed by the participant during screening

3. Have over 50% of trials that have a reaction time of under 200 ms.

    a) Checked during data cleaning

5.5 MEASURES

Assessments will be conducted at baseline, during the task (at intervals of 10 to 60 seconds), at the end of the task immediately and up to 10 minutes later.

Self-reported measures will be completed via directly into the technical platform. More information about the technical platform can be found in section 7.1.1. For the specific time points of administration of each measure, see **Table 1**.

Table 1. Assessment points for each outcome.

Measure	Baseline	End of Main blocks	End of negative section of challenge block
SPIN social anxiety measure	✓		
LSAS-SR social anxiety measure	✓		

PHQ-8 depression measure	✓		
GAD-7 Anxiety measure	✓		
BIQ BDD measure	✓		
Momentary affect	✓	✓	✓
Adverse events Questionnaire			✓

5.5.1 BASELINE MEASURES

Assessment of social anxiety symptoms

The SPIN social anxiety measure will be used as a screening tool and we will include participants scoring above 19 (Connor, 2000).

Social anxiety (SPIN)

The Social Phobia Inventory (SPIN) measures the severity of social anxiety through 17 items, each rated on a 5-point scale, with the response options 0 (“none”), 1 (“a little bit”), 2 (“somewhat”), 3 (“very much”) and 4 (“extremely”). Total scores range from 0 to 68, with scores above 19 indicating a need for further clinical evaluation (Connor, 2000).

Social anxiety (LSAS-SR)

The Lebowitz Social Anxiety Scale – Self-Report; LSAS-SR is calculated adding scores of 0, 1, 2 and 3, to the options “Never”, ”Occasionally”, “Often” and “Usually”, respectively. Total score of the LSAS ranges from 0 to 144. Scores of 0-29 indicate no social anxiety; 30-49 mild social anxiety; 50-64 moderate social anxiety; 65-79 marked social anxiety; 80-94 severe social anxiety and 95-144 very severe social anxiety. A score of ≥30 indicates social anxiety and a score of ≥60 indicates generalized social anxiety. (Fresco et al., 2001; Leigh, et al., 2022)

Other self-report measures

The following questions and questionnaires will be used (they have all been extensively validated and standardised as reported in the publications linked here, and we remove any questions relating to death or suicide):

Depression severity (PHQ-8)

This is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of “Not at all”, “Several days”, “More than half the days”, and “Nearly every day”, respectively. PHQ-8 is the same questionnaire as the PHQ-9 but omits the 9th question

about suicidal thoughts and self-harm. The total score for the eight items included ranges from 0 to 24. Scores of 5, 10, 15, and 20 represent cut- points for mild, moderate, moderately severe and severe depression, respectively (Kroenke et al., 2001).

Anxiety (GAD-7)

This is scored in the same way as PHQ-8. GAD-7 total score for the seven items ranges from 0 to 21. Scores of 5, 10, and 15 represent cut-points for mild, moderate, and severe anxiety, respectively. When screening for anxiety disorders, a recommended cut-point for further evaluation is a score of 10 or greater (Spitzer et al., 2006).

Body Dysmorphic Disorder (BIQ)

The Body Image Questionnaire (BIQ) is a self-report measure of severity of BDD symptoms (Veale et al., 2012). The first question, not included in the final BIQ score, asks about the area(s) of appearance concern. This is followed by 9- items, which are added up to a final score. Items are rated on a 0 to 8 Likert scale, yielding a total score ranging from 0 to 72. A cut-off score of 40 have been shown to indicate clinically significant symptoms (Veale et al., 2012).

5.5.2 PRIMARY OUTCOME

Momentary anxiety

The primary outcome will be momentary anxiety by subjective report (visual analogue scale from 0 -100 for from 0 ‘very relaxed’ to 100 ‘very nervous/uncomfortable’) at the end of the two ‘main’ blocks. Anxiety measured in this way has been the mainstay of experimental studies of social anxiety (Leigh, et al., 2020; 2021)

5.5.3 SECONDARY OUTCOMES

Momentary mood

Secondary outcomes include momentary mood, also measured by subjective report (visual analogue scale from 0 -100 for from 0 ‘very unhappy’ to 100 ‘very happy’). In our research group, we have recently validated this kind of mood ratings against semi-structured interviews (Keren, et al., 2021). We will take the 5-trial average at the end of the two ‘main’ blocks.

Resilience to negative feedback

Resilience to negative feedback within the task. Following a short break, during which participants complete a brief filler task (the Speed of Comprehension Test, 1–2 minutes), both groups will complete a third 'challenge' block consisting of negative feedback, designed to test resilience. The block will conclude with 5 positive trials. Resilience will be measured by looking at the 5-trial average mood and anxiety at the end of the negative section of this block.

5.5.4 OTHER MEASURES

Demographic data – self-reported

At baseline, the participant will answer an online questionnaire designed by the research team asking about the following characteristics:

- age
- gender
- ethnicity
- mental health diagnosis and medications based on self report
- baseline outcomes (screening, primary and secondary)

Audio and video recordings

Audio and video recordings will be collected using GDPR compliant devices and software and stored on DSH. The recordings will be stored securely in DSH for the duration of the project and then destroyed.

Adverse events

Potential adverse events will be monitored in various ways over the total duration of the trial (90 minutes). See section 9 for detailed information of how such events are monitored and handled.

6 PROCEDURE

6.1 RECRUITMENT

6.1.1 RECRUITMENT RATE

Recruitment is planned to be conducted throughout a 24-month period. Our sample size calculations show we need to recruit 550 participants (accounting for a 20% attrition). The 24-month period is in practice a 19-month period, if subtracting 2.5 months each year when potential participants are on holidays (6 weeks during summer and 4 weeks around Christmas and Easter). During these 19 months, the average recruitment rate needs to be approximately 22 participants per month. As there is often a lag period at the beginning of recruitment, we anticipate a slightly slower start to recruitment. Further, we anticipate that recruitment from online testing platforms such Testable Minds, CloudResearch, or Prolific, will allow for a faster recruitment pace, so recruitment may be completed in a shorter time frame than planned.

6.1.2 SCREENING AND RECRUITMENT PROCEDURES

For this trial, we are going to recruit individuals aged 18-25 years who experience elevated symptoms of social anxiety as assessed by the SPIN (Connor, 2000). Participants will be recruited from the community (e.g. UCL campus) through physical flyers and advertisements online as done before (Leigh, et al., 2020; 2021). The SPIN social anxiety measure will be used as a screening tool and we will include participants scoring above 19.

We will recruit people through a) local communities (aged 18-25: tested online or in person), b) via online testing platforms such Testable Minds, CloudResearch, or Prolific (aged 18-25; tested online). These are online platforms commonly used for these research purposes. Online participants will be screened for social anxiety immediately before they complete the intervention. Screened-out participants will be branched out and will be compensated £0.80 for their time.

On online testing platforms (e.g., Prolific), the study will be advertised with an option for participants to click through to a page containing the online information sheet. For the remaining groups, the flyers will have a corresponding QR code that enables participants to enter their contact details (using the secured Microsoft Forms from UCL's office 365 or REDCap linked to Data Safe Haven [DSH]) and find the relevant information sheets to read. All participants will be able to take as long as they need to read and contemplate the study information sheet and ask the research team questions either in person or via email. For participants recruited through online platforms, they will have the option to proceed immediately to screening. For individuals recruited via local communities, at the point of reading the information sheet, they will provide their contact details (on Microsoft Forms or REDCap) and then proceed directly to screening if applicable. Participants who provide identifying information (e.g., contact details) will be allocated a random ID. When these participants are later contacted and invited to complete testing, they will be sent the study link as a URL and will use their random ID to complete testing (see Figure 1). The document linking identifying data to these random IDs will be stored securely on DSH.

For local community participants, screening may be used to match people in experimental tasks involving conversations/interactions with others and inform future sampling. There will not be a separate screening stage for local community participants, We may also use branching logic within the online experiments which will direct individuals to complete suitable tasks based upon their levels of social anxiety.

Consent will be taken either in person (at UCL 1-19 Torrington Place for local community participants) or online (for community or online testing platform participants)..

In the information sheets and at the end of the study, all participants will be provided with information about how they can access mental health support via charities, NHS services, or university services.

6.2 RANDOMISATION, ENROLMENT, AND MASKING

Participants will first be stratified based on their SPIN scores prior to randomization, with strata defined as follows: moderate social anxiety (SPIN scores 19–30), severe social anxiety (SPIN scores 31–40), and very severe social anxiety (SPIN scores >40). Within each SPIN score stratum, participants will then be randomly assigned to either the intervention or control condition using a computer-generated randomization procedure implemented in JavaScript. For each participant, a random number between 0 and 1 will be generated, and participants will be assigned to conditions based on whether the generated number is greater than or less than 0.5. This procedure ensures random allocation within each severity stratum and controls for baseline differences in social anxiety severity across conditions.

The two tasks are identical in all respects, including visual and procedural aspects such as, graphics, design of social interventions, timing and phrasing of prompts and feedback, except in the feedback that participants receive, also ensuring blinding of participants to the assigned condition.

The data management group will provide the investigator team with data where the group variable is coded using random letters (e.g., D, G) thus ensuring analyst blindness.

All procedures will take place over a single session (around 1 hour duration).

All study personnel that can be blind to study aims/hypotheses and group allocation, will be blind, the study statistician will also be blind to the group allocation and will receive the reduced dataset that is required for analysis with blinding in relation to the group allocation.

Masking is guaranteed through the following steps:

Allocation to each group happens algorithmically via a script that runs automatically on a platform.

The two conditions are identical in all aspects with the exception of the difference in the social feedback received.

The primary analysis will be performed after the trial's final participant has finished their final assessment (primary endpoint) and no longer than 90 minutes from entry into the study.

When the statistical analyses are completed, and before unblinding, different versions of the abstract will be written, each reaching different conclusions (e.g., intervention A is superior to intervention B, or vice versa).

Given the brief and low-risk nature of the intervention, a procedure for emergency unblinding is not required.

6.3 INTERVENTION

Both the active and control tasks are Internet-delivered, using an online platform to present the participants with a sequence of social interactions and instructions. Preview versions of both tasks will be made publicly available to facilitate reproducibility.

Both tasks are designed to be as closely matched as possible in terms of length (text to read) and interactivity (format, frequency, and amount of user-required input).

6.3.1 ACTIVE ARM

The intervention is inspired by the success of cognitive therapy for social anxiety, leading to a reduction of both anxiety and depressive symptoms in those patients. It is predicated on the idea that positive social surprises are the mechanism that leads to this improvement: positive social surprises are outcomes in a social situation that are better than one expects. Our intervention seeks to emulate such social situations to test this hypothesis and its usefulness for patients.

Participants will be sat in front of a computer and will interact with three virtual players across three blocks during the task. On each trial, they will first rate their expectation of how positively they believe the virtual player will rate them. Next, they will respond to a self-referential question while being video recorded for 15 seconds. Afterward, they will receive feedback from the virtual player and then report their current mood and anxiety. Importantly, the feedback will gradually change across blocks: for the two 'main' blocks the feedback given by the will improve throughout the block, mirroring a common real-world social dynamic, whereby social reward increases the longer one remains in an interaction (e.g. meeting a stranger who initially feels neutral but becomes progressively more engaged over time). In a third, 'challenge' block, participants will interact with a third virtual player and receive a sequence of negative feedback. This block serves the purpose of testing

affective resilience to negative feedback following the main blocks of the intervention. The third block will end with 5 trials of positive feedback.

6.3.2 ACTIVE CONTROL ARM

The active control arm will be identical in all respects to the intervention except the feedback in the two 'main' blocks will be overall neutral. Specifically, feedback will be fluctuating around a mean of 50%. The third, challenge block will be identical to the intervention arm.

6.3.3 TRAINING, SUPERVISION, AND MONITORING

All trial personnel have been trained in:

Operation of computer systems for conducting the trial.

Safety procedures (see safety protocol below) online.

6.4 END OF TRIAL

The trial will end when the final participant has reached their last assessment which will be no longer than 90 minutes after the last participant enters the study.

6.5 PARTICIPANT WITHDRAWAL FROM TRIAL

Participants are free to withdraw from the trial at any point. If participants indicate to the research team that they would like to withdraw from the trial, all the data that they have provided will be deleted, and they will not be contacted in the future by the research team. Once participants have withdrawn from the trial, it will not be possible for them to re-enter or resume treatment. Withdrawn participants will not be replaced.

6.6 DISCONTINUATION OF TRIAL

Outcome measures will not be analysed until the last participant reaches the primary endpoint and will therefore not inform decisions to stop the trial. However, serious adverse events (see section 9.1) will be reviewed and, if there is any indication that these are linked to the intervention, consideration will be given to discontinuing the trial on the advice of trial Sponsor.

6.7 QUALITY CONTROL

The trial will be conducted according to Good Clinical Practice (GCP) principles. Data quality and safety aspects will be regularly monitored by the Trial Management Group and will be referred back to the Trial Steering Committee for discussion as appropriate (please see below). Weekly meetings are planned to ensure that trial procedures are being followed.

7 DATA MANAGEMENT

All aspects of data management of the trial will comply with the General Data Protection Regulation (GDPR) and Good Clinical Practice (GCP) principles.

7.1 DATA COLLECTION AND HANDLING

Data management measures that are in place to adequately manage and protect the data are: All personally identifiable data will be kept on UCL's Data Safe Haven (DSH), in a section that is only accessible to the study team. Personal data will never exit UCL's servers and will never be used in any publication or other communication of results, results or data to be published will be stripped of any identifiable information.

Participants who provide personally identifiable information via Microsoft forms or REDCap will be allocated randomly generated IDs and will later be invited to complete the study using these random IDs. This will keep their special category data anonymous. The data collected on the online testing platforms does not include information such as name, email, address, or IP, as participants use a randomly generated ID when completing these tasks. Hence all data outputs from the mental health questionnaires, computerised tasks will be pseudonymised at the point of collection and collected using UCL laptops (for in person testing) or using a web browser hosted on the Pavlovia (using PsychoPy) or Gorilla platforms. These data will first be stored on encrypted UCL laptop hard drives, and then securely transferred to the UCL N/S drives, while further raw and pseudonymised questionnaire data (including mental health data) will be stored on DSH.

Primary investigators will remain blinded to group assignment (who received which task, intervention or control) and all data for core analysis. Blinding will be applied at the level of the online experimental platform, ensuring consistency across recruitment sources (Prolific, local community). Allocation to arms will be automated via code-based randomization within the platform and concealed from investigators. The randomization algorithm will be controlled by an external investigation group. During sessions, investigators may monitor participant progress only to troubleshoot technical issues or check completion status; this monitoring will not reveal allocation, as all group assignment and branching logic will be

handled in the experiment code. Investigators will avoid viewing participant screens in-session, except when necessary for technical support or clarification of instructions.

Investigators will have no rights to view or download raw trial data from the experimental platform. Only a data manager, designated from an external investigation group and blind to the purpose of analyses, will be able to view, download and store raw data. The data manager will only be able to disclose information regarding data integrity to the primary investigators if needed. After all experimental sessions are completed, the data manager will download the data and recode group labels using random letters to ensure they are not linked to the actual experimental conditions. The primary research group will remain blinded to these labels throughout the core analysis process. The data manager will share only participant ID, recoded group variable, and baseline and post-outcome measures with the primary research group before the core analysis step.

The primary investigators will execute a pre-specified, automated analysis script, deposited and timestamped in a dedicated GitHub repository to prevent untracked changes. Core analyses will be conducted while investigators remain blinded to group labels. Precision estimates and effect sizes interpretations will be pre-registered and pre-defined in the Statistical Analysis Plan. Unblinding may occur only after the core analyses are complete. Following this, the data manager may share trial-level data with the primary researchers for secondary analyses or computational modelling requiring data inspection. Any unplanned unblinding must be approved by the external group and documented.

7.1.1 TECHNICAL PLATFORM

The questionnaires and tasks will be hosted and administered using the Gorilla Experiment Builder (Gorilla.sc), a cloud-based research platform designed for behavioural science and compliant with key data protection standards. Gorilla provides a secure environment for delivering web-based experiments.

Only pseudonymised data will be collected on Gorilla. Participants will access tasks using a randomly generated study ID or their prolific ID. No personally identifiable information (including names, email addresses, IP addresses) will be collected or stored on Gorilla.sc.

Task data collected on Gorilla will be stored temporarily on the platform's secure servers and will be accessible only to authorised members of the study team via password-protected accounts.

7.1.2 VIDEO CONFERENCE SOFTWARE

For the part of the intervention including video, we will use Gorilla (see previous section), which provides a secure environment for delivering web-based experiments.

8 STATISTICAL ANALYSIS

8.1STATISTICAL PRINCIPLES

8.1.1 ORGANISATION OF DATA AND DATA ANALYSES

A statistical analysis plan (SAP) will be finalised and approved prior to commencing analysis. The programs and code to be used for statistical analyses will be prepared prior to unblinding as far as possible. A statistician will perform the primary analysis independently.

Prior to database lock, basic checks will be performed by the statistician on the blinded data to ensure completeness and accuracy. Outcome variables (primary and secondary), baseline demographic variables and key date variables will be checked for:

- missing values
- values outside an acceptable range
- other inconsistencies

If missing values or other inconsistencies are found, the corresponding data will be sent to the Trial Management Team for checking and will either be corrected, deemed to be missing or confirmed correct, as appropriate.

8.1.2 CONFIDENCE INTERVALS AND P-VALUES

All statistical tests will be two-sided. All estimates will be presented with two-sided 95% confidence intervals and inference on coefficients of interest in regression models will be made on the basis of their respective p-value. For the primary outcome, $\alpha = 0.05$.

8.1.3 ADHERENCE TO INTERVENTION

Adherence to the intervention is defined as completion of more than 50% of the trials of the task.

8.1.4 ANALYSIS POPULATIONS

The ‘intention-to-treat’ population will include all randomised participants according to the treatment to which they were randomised to receive. Any participants that have withdrawn

from the trial, and withdrawn permission to keep and use their data, will be necessarily excluded.

8.2TRIAL POPULATION

8.2.1 RECRUITMENT AND RETENTION

A CONSORT diagram will be presented to provide a detailed description of participant numbers at each time point during the trial. In addition, a table summarising the number of participants who have been lost to follow up at each stage of the trial and reasons for loss to follow up (if supplied) will be presented.

8.2.2 BASELINE CHARACTERISTICS

The demographic information collected at baseline will be presented in a table summarised separately by study arm. Categorical variables will be reported as counts and percentages. Continuous variables will be summarised as either means and standard deviations (SD) or medians and interquartile ranges, depending on the distribution of the data. No statistical tests will be performed to assess baseline differences between study arms. In addition, all baseline outcomes (screening, primary and secondary, see Table 1) will be presented in a table summarised separately by study arm. Please see section 5.5.4 in the Measures section for details on what characteristics will be summarised.

8.3. STATISTICAL ANALYSIS PLAN

8.3.1. PRIMARY OUTCOME ANALYSES

We follow standard recommendations for the analysis of RCTs (Vickers, et al., 2001) using an ANCOVA formulation implemented in a mixed effects model as described below.

The population level measure is the mean difference between the two groups in the primary outcome:

$$\vartheta = E\left[Y_{iSurprise} - Y_{iRandom}\right] (1)$$

And the contrast of interest is:

$$H_0: \vartheta = 0 \quad vs. \quad H_1: \vartheta \neq 0 \ (2)$$

The estimator is:

$$Y_{i,END} = \beta_0 + \beta_1 Treatment_i + \beta_2 Y_{i,0} + \beta_3 Source_i + \varepsilon_i \quad (3)$$

Where Y_i,END and Y_i,0 are the primary outcome at the end of the intervention and at the start of the intervention respectively, Treatment_i indicates participant membership to either the Surprise or the Random arm, and Source_i indicates the source of the participant (0 = UCL, 1 = online).

The measure of interest is estimated through the coefficient of Treatment:

$$\hat{\vartheta} = \hat{\beta_1}$$

The estimated intervention effect, the fixed effect coefficient of the interaction between treatment and time, will be reported with a 95% confidence interval and p-value.

8.3.2. MODEL CHECKING

All modelling assumptions will be checked. In particular, a confirmatory analysis will be performed using the heteroscedastic model which allows the residual variance for intervention and control groups to differ.

8.3.3. SECONDARY OUTCOME ANALYSES

The effect of the intervention on secondary outcomes will be assessed using analogous methods to those used for the primary outcome. P-values will not be reported for secondary analyses. These analyses will be considered supportive.

8.3.4. EXPLORATORY ANALYSES

We will explore whether total LSAS score and the public speaking factor of the LSAS moderate the primary and secondary outcomes.

8.3.5. SENSITIVITY ANALYSES

We will also analyse the primary outcome (data) using a mixed model with random intercepts, i.e. rather than averaging over the five trials.

8.3.6. SUBGROUP ANALYSES

We will investigate whether the treatment effect differs between participants recruited from the UCL community and those recruited online. To achieve this, we will re-fit the primary analysis model with an additional interaction term between the terms Treatment and Source, then formally test this term.

8.3.7. MISSING DATA

Withdrawals from the study, loss to follow up and other missing outcome data will be summarised separately by randomised group. Potential bias due to missing data will be investigated by comparing the baseline characteristics of participants with and without missing values. Depending on the quantity of missing values, predictors of missingness may be identified. We will then perform a sensitivity analysis that includes these predictors of missingness as covariates in the primary analysis model.

Multiple imputation may also be performed, if deemed appropriate. The imputation model will include outcome data from all time-points, as well as baseline characteristics and any predictors of missingness. The primary analysis model will then be re-fitted using the imputed data.

8.3.8. REPORTING

Analyses will be reported with regard to the CONSORT checklist (Moher, et al., 2012) and with any particular requirements of academic journals and the funders to which the results of analyses are submitted.

8.4 PRIMARY OBJECTIVE:

Summary of baseline data

We will follow the CONSORT guidelines in reporting our data. The demographic information collected at baseline will be summarised and presented in a table, by randomisation arm. Categorical variables will be reported as counts and percentages. Continuous variables will be summarised as means and standard deviations. Following CONSORT recommendations,

no statistical tests will be performed to assess baseline differences between study arms (Moher, et al., 2012).

Primary outcome analysis plan

We will use the following ANCOVA analysis model

$$Y_{i,END} = \beta_0 + \beta_1 Treatment_i + \beta_2 Y_{i,0} + \beta_3 Source_i + \varepsilon_i \quad (5)$$

where $Y_{i,END}$ and $Y_{i,0}$ are the primary outcome at the end of the intervention and at the start of the intervention respectively, $Treatment_i$ indicates participant membership to either the Surprise or the Random arm, and $Source_i$ indicates the 'source' of the participant (0=UCL, 1=online). The measure of interest is estimated through the coefficient of Treatment ($\hat{\vartheta} = \hat{\beta}_1$) and the test of interest is:

$$H_0 : \vartheta = 0 \quad \text{vs.} \quad H_1 : \vartheta \neq 0$$

Analysis of secondary outcomes

The effect of the intervention on secondary outcomes will be assessed using analogous methods to those used for the primary outcome. Most of the secondary outcomes are numerical and hence will be analysed using a similar model to that used for the primary outcome, whereas the binary outcomes will be analysed using a logistic regression model. P-values will not be reported for secondary analyses. These analyses will be considered supportive.

8.5 INTERIM ANALYSIS

There are no interim analyses planned.

9 ADVERSE EVENTS

9.1 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

An Adverse Event (AE) is any untoward occurrence to a subject receiving an intervention which does not necessarily have a causal relationship with the intervention. An AE can be any unfavourable and unintended sign, symptom or disease temporally associated with receiving the intervention, whether or not is related to it.

Each AE is to be classified by the Principal Investigator as serious or non-serious. Seriousness is not defined by a medical term; it is a result or an outcome. An AE is defined as a Serious Adverse Event (SAE) if it:

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- is otherwise considered medically significant by the investigator

9.2 EXPECTED ADVERSE EVENTS

As this is a minor intervention, a simple computer game, and participation in the trial only lasts for a maximum of 90 minutes, we have no reason to expect any adverse events and there is no prior literature to suggest otherwise. We have run pilot experiments in 584 participants so far using interventions identical to or very close to what we intend to trial here. So far no adverse events have been identified either through observation or open text or any other communication with participants. This yields a zero numerator and based on standard statistical considerations (rule of three, CITE) the upper risk estimate (95% CI) of any adverse event can be estimated as being 0.005.

9.3 RELATED ADVERSE EVENTS

The assessment of the relation between adverse events and the administration of the intervention is a decision based on all available information. The final decision is taken by the Principal Investigator. If the event is a result of the administration of any of the research procedures, then it will be classed as related.

All AE will be categorized in accordance with the definitions below:

- **Likely related:** Clinical event occurring within a reasonable time after administration of the intervention. It is unlikely that the event can be attributed to underlying disease or medications but is most likely caused by the intervention.

- **Possibly related:** Clinical event occurring within a reasonable time after administration of the intervention. The event could be explained by the intervention, but there is insufficient information to determine the relationship. The event could be explained by an underlying disease or medications.

- **Not related:** Clinical event that is not reasonably related to the intervention. The event is unlikely related to the intervention and can be explained by medications or underlying disease.

9.4 HANDLING OF ADVERSE EVENTS

Given the nature of the data collection and the short duration of the trial which is only 90 minutes, assessment of adverse events will be possible in the following ways.
Please note that we have removed from the screening questionnaires any items that could be particularly distressing such as questions relating to suicide, suicidal ideation/thoughts and thoughts about death or trauma.
Please also note that a consultant child and adolescent psychiatrist (Prof Stringaris) or clinical psychologist (Prof Krebs) are always reachable by the research team to manage any clinical risks arising.

Remote sessions for local community participants

Before the intervention, students are informed that they can tell the researchers at any point if they would like to stop the session, for any reason and that their compensation will not be impacted. In remote sessions, researchers will remotely monitor participant progress, and participants will be able to contact researchers via phone or email should any problems occur. This will then be recorded by the research using a tick list and open-end reporting.
During the in-person sessions, researchers will visually monitor and record any visible distress and receive any comments from young people in relation to distress.
At the end of the trial (after a maximum of 90 minutes per participant), and before the research teams leave, the students will be reminded that they can write to the researchers should any problem arise.

Sessions for Prolific participants

Before the intervention, participants are informed that they can stop the session, for any reason. They are also informed that should any problem arise, they can communicate with the researcher for any issues.

For all sessions:
At the end of the task, participants are asked to give feedback, including to rate how they felt during the intervention, from 0 (Very Upset) to 100 (Very Happy). If participants score <= 50, they are then asked to report what it is that upset them during the task. This feedback will be monitored by the Data Monitoring Committee (DMC).

For prolific sessions, the following text is displayed at the end of the experiment:

"Speak to your GP (UK) or Primary Care Doctor (US) and discuss how you are feeling.

Your GP or doctor can assess how you are feeling and talk through possible options with you, including support, treatment, and referrals if needed.

UK Resources

Mind
This charity provides helpful information about getting support for mental health problems and accessing services in the UK.

Website: mind.org.uk

The Mix & Samaritans
These nationwide charities offer support and advice. Samaritans is available 24 hours a day, every day of the year. The Mix also provides support groups, discussion forums, and counselling services tailored to young people.

- Text **THEMIX** to **85258** or visit **themix.org.uk**
- Call **Samaritans: 116 123** or visit **samaritans.org**
- NHS mental health information: **nhs.uk/mental-health**

If you are experiencing an urgent mental health crisis in the UK, call **NHS 111** and select the Mental Health option to speak with a trained mental health professional.

US Resources

988 Suicide & Crisis Lifeline
A free, confidential support service for people experiencing emotional distress, mental health crises, or needing immediate support. Available 24 hours a day, every day of the year across the United States.

- Call or text **988**
- Visit **988lifeline.org**

NAMI (National Alliance on Mental Illness)
Provides information, support, education, and resources for mental health concerns, including support groups and helplines across the United States.

- Call **1-800-950-NAMI (6264)**
- Visit **nami.org**"

For local community sessions, the following text is displayed at the end of the experiment:

"Speak to your GP (UK) or Primary Care Doctor (US) and discuss how you are feeling.

Your GP or doctor can assess how you are feeling and talk through possible options with you, including support, treatment, and referrals if needed.

UK Resources

Mind
This charity provides helpful information about getting support for mental health problems and accessing services in the UK.

Website: **mind.org.uk**

The Mix & Samaritans
These nationwide charities offer support and advice. Samaritans is available 24 hours a day, every day of the year. The Mix also provides support groups, discussion forums, and counselling services tailored to young people.

- Text **THEMIX** to **85258** or visit **themix.org.uk**
- Call **Samaritans: 116 123** or visit **samaritans.org**
- NHS mental health information: **nhs.uk/mental-health**

If you are experiencing an urgent mental health crisis, please call **NHS 111**, which has a Mental Health option that allows you to speak with a trained mental health professional.

If you are a UCL student, you can contact **UCL Student Support and Wellbeing Services** on **+44 (0) 20 3108 8836**."

All adverse events will be noted by the trial's research assistants in a specific log (including date, and a brief description of the event), which in turn will be shared with the PI who will evaluate them according to their severity. Should an SAE arise, the investigator will notify the Sponsor and the TSC.

10 DATA SHARING

Non-identifiable data will be kept on secure UCL servers and UCL computers with access restricted to the research team. After the study, the anonymised data, that is not subject to data protection legislation, will be transferred to GitHub where it can be accessed by other researchers. This is a requirement for publication in some journals and is consistent with good open science practice.

11 ETHICAL CONSIDERATIONS

Overall, the risks for the participants are expected to be absent or very low given both the mild nature of the intervention and its very short duration (90 minutes maximum). The potential benefits for the participants and the scientific value of the study far outweigh the potential risks of participation.

As part of this study, we will collect and use personal data including special category data such as data concerning mental health data and video recordings, for which explicit ethical informed consent will be sought. The lawful basis for processing will be “task in the public interest” and “scientific research purposes” for special category data.

Participants will complete mental health questionnaires in the screening and testing sessions. These questionnaires will only be completed individually. As explained in Section 9, questionnaires have been adapted to avoid items that could be distressing. Please also note the procedure that is established for dealing with adverse events.

12 IMPLICATIONS

Our vision is to discover a fundamental mechanism that underlies how we can influence young people’s social anxiety and translate these insights back into clinically useful knowledge that is ethically viable and acceptable to young people.

13 FUNDING

The trial has received funding from the Wellcome Trust [226785/Z/22/Z]

14 PUBLICATION PLANS

We plan to publish one or two primary papers. The main paper will report on the efficacy of the intervention. Additional papers may include analysis of predictors and moderators of treatment outcome. All manuscripts will be submitted to general or specialist medical and psychological science journals.

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16 APPENDIX

SURPRISES STUDY GENERAL RISK PROCEDURES

Principal Investigators (PIs):
Prof A Stringaris (Consultant Child & Adolescent Psychiatrist, GMC: 6043066), a.stringaris@ucl.ac.uk; 07514851520

Prof G Krebs (Clinical Psychologist, HCPC Registered Practitioner Psychologist: PYL06286); g.krebs@ucl.ac.uk; 07968 963857

Procedure

<u>During the visit/call</u>

- If spoken to, listen actively and respectfully.
- Do not probe for risk, but mindful of:
    - Disclosures of harm (self-harm, suicidal thoughts, abuse).
    - Indications of intense distress or hopelessness (e.g. crying).

Responding to indication of potential risk

- Stay calm and non-judgmental
    - Acknowledge the concern.
    - Do not make promises of confidentiality. Explain calmly and clearly that *"Because I'm concerned about your safety, I will need to speak to someone who can help, we can think together about who that might be."*
    - Do not assume a clinical role or probe further.
    - One of you should discuss with one of the PIs any concerns from this session.

After the call

- Document the concern clearly in our Events Log sheet:
    - What was said/observed
    - Who said it (incl. Participant ID)
    - Who it was reported to and any steps that were taken.
    - Time and date
- Discuss with PIs any remaining concerns
    - Phone or secure message (within 30 minutes)
    - PI will advise on next steps.

The above principles also apply to visits in-lab at UCL.