STUDY PROTOCOL

Effects of reducing appearance-related behaviours on body dysmorphic disorder symptoms in university students: A randomised controlled trial

Long title of the trial	Effects of reducing appearance related behaviours on body dysmorphic disorder symptoms in university students: A randomised controlled trial
Short title of the trial	Reducing Excessive Focus on self-appearance by LEarning Cognitive behavioural Techniques (REFLECT)
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Signature

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Summary

Title	Effects of reducing appearance related behaviours on body dysmorphic disorder symptoms in university students: A randomised controlled trial
Short title	Reducing Excessive Focus on appearance by LEarning Cognitive behavioural Techniques (REFLECT)
Objectives	To evaluate the efficacy, feasibility, acceptability and safety of a brief intervention (REFLECT), which is a psychoeducational video and therapeutic instruction that aims to improve elevated but subthreshold body dysmorphic symptoms by targeting appearance related behaviours. The REFLECT intervention will be compared to an active control, which is a psychoeducational video and therapeutic instruction focused on sleep hygiene. Specific objectives are as follows i) To evaluate efficacy, change in body dysmorphic symptoms in the intervention versus control conditions will be estimated. ii) To evaluate feasibility, rates of recruitment and retention into the single session intervention and control condition will be calculated. iii) To evaluate acceptability, acceptability will be assessed with a quantitative measure and explored using qualitative interviews. iv) To evaluate safety, proportions of participants reporting negative effects in the intervention and control condition will be calculated.
Type of trial	Parallel-group, single blind, randomised superiority trial with nested qualitative study
Rationale for the study	Indicated primary prevention interventions for body dysmorphic disorder (BDD) are currently lacking. Initial evidence suggests that isolating and adapting components from cognitive behavioural therapy (CBT) for BDD into brief interventions may be suitable strategy for developing such preventative interventions. Before evaluation as a primary prevention intervention, evidence of efficacy, feasibility, acceptability and safety must be demonstrated.

This randomised controlled trial (RCT) will evaluate whether a brief digital intervention (REFLECT) based on CBT for BDD is efficacious, feasible, acceptable and safe at improving body dysmorphic disorder symptoms relative to an active control.

Trial design and methods

The design is a parallel group, single (i.e., researcher) blind randomised superiority trial with nested qualitative study. The study will include individuals with elevated but subthreshold body dysmorphic disorder symptoms assessed using a validated self-report measure.

The study will compare a brief intervention (REFLECT) with an active control. The intervention will involve a psychoeducational video and therapeutic instructions, informed by cognitive behavioural techniques from CBT for BDD (intervention condition) to an active control. The control will involve psychoeducational video and therapeutic instructions informed by cognitive behavioural techniques from CBT for insomnia (active control condition) but will be framed as an intervention by explaining to participants the impact that poor sleep can have on anxiety, including appearance anxiety.

All participants will be screened for eligibility before consenting for this study as part of a separate universal screening study of body dysmorphic disorder symptoms via local community. Participants screened as eligible will be randomised to either the intervention condition or control condition in a 1:1 ratio.

Participants will complete all outcome measures within REDCap over a total of four weeks. REDCap is a digital data collection tool commonly used for epidemiological research studies. Specifically, participants will be asked to complete:

- Baseline questionnaires (completed during as part of a linked screening study, before consenting into this trial and before condition assignment).
- Credibility and expectations questionnaire (completed following condition assignment and after watching the therapeutic video).
- Weekly questionnaires measuring appearance related behaviours (intervention condition) or sleep hygiene behaviours (active control condition).

- Follow-up questionnaires (completed at two and four weeks following baseline).
- Acceptability questionnaire (completed at four weeks following baseline).
- Retention rates to the study.

All questionnaire measures are self-report.

The nested qualitative study will explore the acceptability of the intervention procedures from the perspectives of a subgroup of participants who completed and did not complete the interventions.

Participant time in trial	Four weeks
Total trial duration	Approximately 12 months
Planned trial sites	University College London
Brief eligibility criteria	Eligible participants will: • Be aged 18+. • Score between 20 and 39 on the Body Image Questionnaire (BIQ). • Be a UCL registered student. • Not be taking any new or have changed medications for a mental health condition within the previous six weeks.
Statistical methodology and analysis	The aim is to evaluate the efficacy, feasibility, acceptability and safety of the REFLECT intervention in improving primary and secondary outcomes compared to an active control condition. This study protocol will be registered prior to starting recruitment to the trial on the ISRCTN The UK's Clinical Study Registry. The statistical analysis plan will be pre-registered prior to accessing the data and analytic code will be published on GitHub before data collection is complete, to reduce risk of bias. Standard recommendations for the analysis of RCTs using an ANCOVA formulation will be used, as described below.

1. Overview

Indicated primary prevention interventions, or activities aimed at reducing the incidence of mental disorders (Fusar-Poli et al., 2021), such as body dysmorphic disorder (BDD), are sparse. Initial evidence suggests that isolating and adapting components from Cognitive Behavioural Therapy (CBT) for BDD into brief interventions may be a suitable strategy for developing such preventative interventions (Patel & Cougle, 2024). Before evaluation as a primary prevention intervention, evidence of efficacy, feasibility, acceptability and safety must be demonstrated.

This randomised controlled trial (RCT) will evaluate whether a brief intervention based on CBT for BDD is efficacious, feasible, acceptable and safe at improving body dysmorphic disorder symptoms relative to an active control. The study will not establish whether this brief intervention prevents the onset of BDD but will provide crucial evidence to decide whether to proceed to large-scale studies necessary to evaluate prevention interventions.

2. Background

2.1. Body Dysmorphic Disorder (BDD) and adverse outcomes

Body dysmorphic disorder (BDD) is a common but debilitating mental health condition, typically emerging in adolescence (American Psychological Association, 2013; Bjornsson et al., 2013). The disorder is characterised by excessive concern with perceived flaws in one's appearance, accompanied by feelings of intense anxiety and shame (American Psychological Association, 2013). An estimated 2% of the population is affected by BDD, and 8.5% of the population report impairing symptoms that do not meet diagnostic thresholds (Krebs et al., 2025). Without intervention, these symptoms usually persist, reducing quality of life and contributing to poor educational engagement and suicide attempts (Addison et al., 2024; Phillips et al., 2013; Phillips, 2000; Rautio et al., 2022). Timely access to effective intervention is crucial to prevent these adverse outcomes.

2.2. Limited access to effective treatment and prevention for BDD

Cognitive Behavioural Therapy (CBT) is a highly effective treatment for BDD, but access is limited and often delayed (Harrison et al., 2016; Zhao et al., 2024). Studies suggest as few as 1 in 100 individuals with BDD receive CBT for BDD in routine healthcare services (Addison et al., 2024; Olaomi et al., 2024; Rautio et al., 2024). By the time treatment is received, symptoms have often worsened to the point that the required intervention is longer and less effective (Phillips et al., 2013). Preventing such adverse outcomes through timely intervention requires improving access to treatment, as well as primary

prevention interventions to reduce the incidence of BDD. However, such prevention interventions are currently lacking.

2.3. Developing effective prevention interventions from CBT for BDD

One approach to developing prevention interventions is to isolate and test 'active ingredients' from effective and evidence-based psychological treatment approaches, namely CBT. One active ingredient within CBT for BDD is exposure and response prevention (ERP), which involves supporting people to confront feared situations without using appearance-related behaviours (Patel & Cougle, 2024; Wilhelm et al., 2013). These behaviours are a criterion for BDD, are involved in the maintenance of BDD symptoms, and may be implicated in other mental disorders, including depression, social anxiety and eating disorders (American Psychological Association, 2013; Bilsky et al., 2022; Summers & Cougle, 2018). There is promising experimental evidence that brief therapeutic instruction to stop appearance related behaviours is effective for reducing appearance related concerns—symptoms which are a diagnostic criterion for BDD—among females recruited from social media (Patel & Cougle, 2024). While promising, improvements in symptoms do not necessarily translate to reductions in the incidence of a disorder. Establishing a preventative effect requires large sample sizes and longer-term follow-up (Cuijpers, 2003). A necessary first step is to replicate findings from promising early studies in contexts where it is possible to conduct large scale evaluation.

2.4. Higher education as context for developing and evaluating prevention

One important context to reach individuals at high risk of BDD at scale is higher education. The typical onset of BDD occurs during adolescence (Bjornsson et al., 2013). Roughly one third of adolescents attend higher education by age 18 and a half by age 25, meaning higher education overlaps with the broader age range in which BDD and elevated but subthreshold symptoms emerge (Bjornsson et al., 2013; OECD, 2022). More directly, estimates suggest the prevalence of BDD is higher among university students compared to the general population (Veale et al., 2016). Higher education, therefore, brings together a population at higher risk of BDD due to age. Higher education also has established service infrastructure, including student wellbeing services, providing a route to recruit, deliver and evaluate interventions at scale (AMOSSHE: The Student Services Organisation, 2023; Hughes, 2019).

2.5. Digital methods as a feasible and acceptable approach to scale prevention

One approach to scaling and improving access to interventions is digitally enabled methods. There is evidence from high-quality observational research that such methods can improve access at scale, especially among social groups less likely to access in-person services (Habicht et al., 2024). Qualitative research indicates these

methods could be valuable to address concerns about confidentiality and disclosure in person services among university students (Byrom et al., 2022; Cage et al., 2020; Priestley et al., 2021). Yet despite the promise of digitally enabled methods as a delivery mechanism, engagement with such interventions is often suboptimal in practice (Lattie et al., 2019; Taylor et al., 2024). These methods are not necessarily straightforward to integrate into students' day-to-day lives, nor do they always align with their preferences. Consequently, efficacy demonstrated in controlled settings may not translate into effectiveness, making it necessary to assess the feasibility and acceptability of any interventions at an early stage.

2.6. Evaluating potential harms from prevention

In addition to efficacy, feasibility and acceptability, promising interventions need to be evaluated for potential harms before scaling. A guiding principle of prevention science is that small improvements in symptoms can translate into a large impact, because small effects are scaled to a large population (Carey et al., 2023; Rose et al., 2008). This carries an important consequence: any harmful effects attributable to an intervention would also be scaled, producing a negative impact at the population level. Plausible harms from psychological interventions include (temporary) increases in distress, as well as reinterpretation of milder or transient distress as a disorder, which may influence how individuals interpret and respond to future difficulties (Foulkes et al., 2024; Foulkes & Stringaris, 2023). Given these possibilities, safety must be assessed to identify any signals of harm before considering larger-scale evaluation necessary to conclude preventative effects.

2.7. Purpose of this study

The purpose of this research is therefore to evaluate the (i) efficacy, (ii) feasibility, (iii) acceptability, and (iv) safety of a digitally enabled intervention for university students with elevated but subthreshold body dysmorphic disorder symptoms.

Participants will be randomly allocated to receive either a brief intervention, called REFLECT, containing psychoeducation and therapeutic instructions to stop appearance-related behaviours (intervention) or a brief intervention containing psychoeducation and therapeutic instructions to improve sleep hygiene (control). Both interventions are explicitly framed as being aimed at reducing appearance concerns, and a credible explanation for this is provided. Both groups will receive daily reminders to complete the therapeutic instructions alongside a short weekly questionnaire.

The primary outcome will be body dysmorphic symptoms at two weeks following baseline. Secondary outcomes will be anxiety levels, depression levels, social anxiety levels, eating disorder symptoms, and functioning, all at two weeks following baseline.

These secondary outcomes evaluate whether the effect of the intervention generalises to anxiety, depression, eating disorder symptoms, social anxiety and functioning.

Feasibility will be evaluated through retention rates in the study at two weeks. Acceptability will be evaluated through an acceptability measure at two weeks following baseline and through qualitative interviews with participants. Finally, safety will be evaluated through a negative effects measure reported at two weeks in both intervention and control conditions and weekly participant reports on intervention effects.

Objectives

1. To evaluate the efficacy of the REFLECT intervention compared to an active control by estimating the between-group effect size difference on body dysmorphic symptoms at two weeks. The effect on secondary outcomes, including depressive and anxiety symptoms, will also be examined.
2. To evaluate feasibility by calculating rates of recruitment and retention to the REFLECT intervention and the control condition.
3. To evaluate the acceptability of the REFLECT intervention and the control condition by measuring acceptability and exploring participants' experiences of the intervention procedures.
4. To evaluate the safety of the REFLECT intervention and the control condition by calculating between-group differences in negative effects.

3. Project description

3.1. Design

The study design will be a parallel-group, single blind randomised controlled superiority trial with a nested qualitative study for university students with elevated but subthreshold body dysmorphic disorder symptoms.

Participants recruited into the study will be randomised to either the intervention or active control condition in a 1:1 ratio.

All participants will complete a baseline assessment as part of a separate screening study, followed by consent to this study, and then randomisation (intervention or control). The trial procedures will take place over a four-week period, with two weeks following baseline as the primary endpoint. All study procedures, except qualitative interviews, take place within the REDCap system.

3.2. Study site

The study will be conducted at University College London. It will be conducted online via the REDCap platform with participants recruited from the University College London community.

3.3. Study population

The study population are adult university students recruited from the UCL community with elevated but subthreshold body dysmorphic disorder symptoms.

Inclusion criteria

1. Aged 18 and above.
2. UCL-registered students.
3. Score on the Body Image Questionnaire (BIQ) of between 20 and 39 (inclusive)

Exclusion criteria

1. BIQ score of less than 20 or 40 or above.
2. New or change in medication for a mental health condition within the prior six weeks.

3.4. Measures

Measures will be completed by participants at baseline (before consenting to this study), following random assignment to intervention or control, each week following baseline, and lastly at four weeks. All participants are recruited via a universal screening study, which will act as the baseline for the trial.

All assessments will comprise self-report measures (see Table 1) which will be completed via the REDCap platform.

Table 1: List of the measures included at each time point and completion times

	Baseline				
Measure	Screening study (5 to 10 minutes)	Following random assignment (2-5 minutes)	Weekly following baseline (1 minute)	2 weeks following baseline (primary endpoint) (5 to 10 minutes)	4 weeks following baseline (5 to 10 minutes)
BIQ body dysmorphic	✓			✓	✓

disorder symptoms measure					
BDD-5 body image screener	✓			✓	✓
PHQ-8 depression measure	✓			✓	✓
GAD-7 anxiety measure	✓			✓	✓
Mini-SPIN social anxiety measure	✓			✓	✓
EDEQ-7 eating disorders measure	✓			✓	✓
WSAS functioning measure	✓			✓	✓
Cosmetics procedures measure		✓			
Appearance Related Behaviours Questionnaire		✓	✓	✓	✓
Sleep hygiene index		✓	✓	✓	✓
TFA acceptability measure		✓		✓	
Credibility and expectancy measure		✓ (following intervention)			
Negative effects questionnaire				✓	✓
Weekly effects measure			✓	✓	✓
Health service use	✓			✓	✓

3.4.1. Description of measures

3.4.1.1. Assessment of body dysmorphic disorder symptoms

The Body Image Questionnaire will be used as a screening tool, and all participants scoring between 20-39 on this tool will be included.

Body Image Questionnaire (BIQ)

The Body Image Questionnaire measures the severity of body dysmorphic disorder symptoms through nine items, each rated on an 8-point scale, with the response options varying based each item (Veale et al., 2012). Total scores range from 0 to 72, with higher scores indicating higher severity of symptoms and scores above 40 indicate a risk for a clinically significant disorder (Veale et al., 2012).

3.4.1.2. Other self-report measures

Depression severity PHQ-8

The Patient Health Questionnaire-8 measures the severity of depression through 8 items (Kroenke et al., 2009). Depression severity is calculated based on scores of 0, 1, 2, and 3 for "Not at all", "Several days", "More than half the days", and "Nearly every day", respectively. The total score for the eight items included ranges from 0 to 24. Established cutoff points for mild is 5, moderate is 10, moderately severe is 15, and severe depression is 20 (Kroenke et al., 2009).

Anxiety GAD-7

The Generalised Anxiety Disorder-7 measures the severity of anxiety symptoms through 7 items (Spitzer et al., 2006). Anxiety severity is calculated based on scores of 0, 1, 2, and 3 for "Not at all", "Several days", "More than half the days", and "Nearly every day", respectively. The total scores range from 0 to 21. Scores of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively. Individuals are considered at risk for anxiety disorders based on a cut-point based on a score of 10 or greater (Spitzer et al., 2006).

Body Dysmorphic Disorder criteria BDD-5

The BDD-5 is a screening measure of agreement with the body dysmorphic disorder criteria based on the 5 items (Möllmann et al., 2017). Responses are "Agree" or "Disagree" to each item.

Social anxiety (mini-SPIN)

The mini-Social Phobia Inventory (mini-SPIN) measures the severity of social anxiety symptoms using three items (Connor et al., 2001). Social anxiety severity is calculated based on scores of 0, 1, 2, 3, and 4 for “Not at all”, “A little bit”, “Somewhat”, “Very much”, and “Extremely”, respectively. Total scores range from 0 to 12. Scores of 6 or higher are indicative of clinically significant symptoms (Connor et al., 2001).

Eating disorder symptoms (EDEQ-7)

The EDE-Q7 measures the severity of eating disorder symptoms over the previous 28 days over 7-items (Jenkins & Davey, 2020). Eating disorder symptoms are calculated based on scores of 0, 1, 2, 3, 5, and 6. Total scores range from 0 to 6, with higher scores indicating greater presence of symptoms and higher risk of clinically significant symptoms (Jenkins & Davey, 2020).

Work and Social Adjustment Scale (WSAS)

The Work and Social Adjustment Scale measures the degree of impairment using five items related to work, home management, social leisure, private leisure, and close relationship (Mundt et al., 2002). Impairment is calculated based on scores from 0 to 8, where “0” refers to “Not at all” and 8 refers to “Very severely impaired”. Total scores range from 0 to 40, with higher scores indicating greater impairment across a greater number of domains. Scores below 10 indicate subclinical populations (Mundt et al., 2002).

Cosmetics procedure measure

Two items to assess whether participants have recently received or are planning to receive a cosmetic procedure. The measure was developed by the trial personnel, worded as “Are you receiving or planning to receive a procedure or medication that is appearance-altering (for example, cosmetic surgery, dermatological treatment, orthodontics, or acne treatment)?”. Participants can respond with either “Yes” or “No”. If " Yes " is selected, then “If yes, please specify” with an open text response is displayed.

Appearance Related Behaviours Scale

The Appearance Related Behaviours Scale measures appearance-related behaviours over the past month due to body dysmorphic disorder symptoms (Patel et al., 2022). Extent of engagement with appearance-related behaviours is calculated based on scores of 0, 1, 2, 3, and 4 for “Never”, “Occasionally”, “Sometimes”, “Often”, and “Always”, respectively. Total scores range from 0 and 52, with higher scores indicating greater engagement with appearance-related behaviours (Patel et al., 2022).

Sleep Hygiene Index

The Sleep Hygiene Index measures the extent of engagement with sleep hygiene behaviours (Mastin et al., 2006). Extent of engagement is calculated based on scores of 1, 2, 3, 4, 5 for “Never”, “Rarely”, “Sometimes”, “Frequently”, “Always”. Total scores range from 13 to 65, with higher scores indicating poorer sleep hygiene behaviours (Mastin et al., 2006).

Theoretical Framework of Acceptability Measure

The TFA measures the extent to which an intervention is acceptable to participants through eight items (Sekhon et al., 2022). Of these eight items, seven items refer to affective attitude, burden, ethicality, perceived effectiveness, intervention coherence, self-efficacy, and opportunity costs, with the eighth item referring to general acceptability. Acceptability is calculated based on scores of 1, 2, 3, 4, and 5. Items for burden and opportunity costs are reverse-scored (Sekhon et al., 2022). The extent to which an intervention is acceptable can be derived using the sum score of the seven items or the score for the eighth item (Sekhon et al., 2022).

Credibility and Expectancy Questionnaire

The Credibility and Expectancy Questionnaire measure the extent to which participants think and feel about credibility and expectations of the intervention through six items (Devilly & Borkovec, 2000). Four items are scored on a nine-point scale with response options varying by item. Two items are scored using deciles. Total scores can be derived by converting each item to z-scores before summing into a sub-scale score for Credibility and Expectancy (Devilly & Borkovec, 2000).

Negative Effects Questionnaire

The Negative Effects Questionnaire (NEQ) investigates potential negative effects of psychological treatments (Rozental et al., 2019). The scale consists of 20 items relating to common adverse events, including: sleeping problems, worse anxiety, and hopelessness about the future. For the REFLECT Trial, the NEQ is adapted by removing references to treatment or therapy and removing seven items which are irrelevant to the study. The scale is therefore made up of 13 items. Each item is rated as either “yes” or “no”. If any items receive a “yes”, then the item is scored on a five-point scale from “not at all” to “extremely” in terms of how negatively it affected the participant (Rozental et al., 2019).

Weekly effects measure

One item, developed by the trial personnel, is included to elicit participant views on the effects of the intervention and capture any positive or adverse effects before the

Negative Effects Questionnaire at two weeks. This is worded as “What, if any, effects have you noticed from the intervention?” Participants can respond using open text.

Other measures

Demographic data

At baseline, participants will be asked to answer questions about the following characteristics:

- Age.
- Sex.
- Gender identity.
- Ethnicity.
- New or change in medication for a mental health condition.
- Health service use in the past month, as health service use could affect the efficacy of the intervention.

Interviews: audio and video recordings

A nested qualitative study will be conducted to explore the acceptability of the structure and activities of the intervention and control condition.

Previous research has shown engagement can be poor with digitally enabled interventions. For example, digitally enabled interventions show mixed retention over the study period (Lattie et al., 2019; Taylor et al., 2024). To explore participants’ experiences and perspectives on the acceptability of the structure and activities of the control and intervention, qualitative interviews will be conducted with a subsample of trial participants from both conditions.

Participants can indicate their willingness to participate in a qualitative interview as part of the consent procedure to the trial. Participants from both conditions who: a) miss weekly measures and measures four weeks following baseline; and b) complete all measures will be identified. Recruitment to the qualitative component will aim for variation by sex and ethnicity by purposively sampling participants from across these categories using demographic information collected in REDCap as a sampling frame. Approximately n~15 participants will be recruited. However, final sample size will be determined by information power, with recruitment continuing until sufficient depth has been achieved (Malterud et al., 2016).

Interviews will be conducted with participants either in person or online (via MS Teams). For both settings, audio and video recordings will be generated via Microsoft Teams and collected on GDPR compliant devices and stored on SharePoint/OneDrive UCL

systems. Participants can opt for audio only. An MSc student will conduct interviews to minimise the risk of unblinding the trial personnel.

3.4.1.3. Adverse events

Adverse events will be assessed using the Negative Effects Questionnaire, which is a 20-item questionnaire for monitoring the adverse effects from psychological interventions, for the total duration of the study (Rozental et al., 2019). Additionally, an increase of 10 points on the BIQ from baseline to follow-up at two or four weeks will be considered an adverse event since this exceeds the threshold for reliable change (National Collaborating Centre for Mental Health, 2018). See section 3.6 for detailed information on how adverse events will be monitored and handled. In addition, at each assessment time point post-intervention, participants will be asked an open question about their experience of the intervention and its effects, with an open-text response format.

3.5. Procedure

3.5.1. Recruitment

3.5.1.1. Recruitment rate

Recruitment to the study will take place over a 12-month period. Sample size calculations show 183 participants need to be recruited, accounting for 30% attrition (see section 4.3.2). During the twelve months of the study, the mean recruitment rate needs to be approximately 16 participants each month, which is expected to be slower in the initial months of recruitment.

3.5.1.2. Screening and recruitment procedures

Participants will comprise university students who report elevated but subthreshold body dysmorphic disorder symptoms as assessed by the BIQ. Participants will be recruited from the community sample using physical adverts, digital advertising on platforms including the UCL learning management system - Moodle, and student mailing lists for selected departments within each faculty of the university.

All participants will be recruited into the trial following a screening study where baseline measures are collected. The design of this screening study was informed by three co-design workshops (n=8 to 10 UCL students each) held in October and December 2025 and January 2026. These workshops aimed to elicit students' views on their needs, preferences and potential solutions to improve recruitment and retention to the study and interventions.

Physical and digital advertisements will include QR codes to enable participants to go directly to the screening study.

Emails will include the link and digital advert, with both enabling the participant to go to the screening study.

In the screening study, participants who score between 20-39 on the BIQ will be able to proceed to the participant information sheet for this randomised controlled trial. Branching logic within the REDCap system will enable this process.

Participants who wish to take part in the study will complete the consent procedure online in the REDCap system to proceed to the trial. All participants will be provided with information about sources of mental health support at UCL, in the NHS and via charities.

3.5.2. Randomising, enrolment and blinding

The random allocation of participants to either the intervention or control condition in a one-to-one ratio will be conducted within the REDCap system. The randomisation list will be generated in an Excel document by a researcher independent of the trial personnel and incorporated into the REDCap module by this researcher. This randomisation list will not be accessible to the trial personnel, reducing the risk of unblinding.

The intervention and control allocation and measures will be concealed within REDCap, thereby ensuring the trial personnel are not unblinded to the intervention assignment.

While participants cannot be blinded to their intervention allocation, the following efforts aim to reduce bias. The intervention and control conditions are similar in terms of credibility scores in a pilot study; credibility scores will be measured following allocation and following delivery of the therapeutic video. Both conditions follow the same structure in terms of activities, timing, form of the therapeutic instruction provided to each participant and the receipt of daily updates for a total of four calendar weeks following baseline.

Due to the brief nature of the intervention, a procedure for emergency unblinding is not required.

3.5.3. Interventions

Both intervention and control conditions will be delivered digitally, whereby participants can access the brief (~5-minute) psychoeducational video and therapeutic instructions via the REDCap system. Both the intervention and control videos and instructions are as similar as possible in terms of length, text to read, structure, and style. In both the

intervention and control condition, the video is followed by daily text reminders over the following four weeks.

3.5.3.1. Intervention condition

The intervention condition is informed by CBT for body dysmorphic disorder, which has demonstrated efficacy in reducing appearance-related behaviours and body dysmorphic disorder symptoms (Abdalla et al., 2026). The intervention is theory-based in that it draws on the hypothesised active ingredients from CBT for BDD (Patel & Cougle, 2024; Wilhelm et al., 2013). A putative active ingredient is exposure and response prevention (ERP), which involves reducing appearance-related behaviours. These behaviours are a criterion for the diagnosis of BDD and are thought to maintain appearance preoccupation (Patel & Cougle, 2024; Wilhelm et al., 2013).

The intervention condition is also informed by pilot data and evidence from a randomised controlled trial (Patel & Cougle, 2024). A single-arm pilot study of the intervention was conducted in July 2026, comprising n=29 participants recruited from Prolific. To approximate the age distribution of UCL students, participants were included if aged between 18 and 30 years old. Participants followed the intervention activities of the planned trial: i) viewed a psychoeducational video and therapeutic instructions and ii) were sent reminders daily for two weeks.

The intervention will be completed by participants either on a computer, tablet or a mobile phone. Within the REDCap platform, participants will be able to view an approximately five-minute psychoeducational video about the role appearance-related behaviours play in maintaining body dysmorphic disorder symptoms. The video concludes with the therapeutic instructions: 1) to identify appearance-related behaviours and 2) to stop appearance-related behaviours over the following four weeks. After the video, a short four-sentence summary of the key points of the video and the task is shown, and participants are asked to take a screenshot of the summary. Participants then receive daily automated text reminders of the task via REDCap for a total of four calendar weeks.

3.5.3.2. Control condition

The active control condition is based upon evidence that sleep hygiene interventions are a transdiagnostic target for reducing internalising symptoms (Freeman et al., 2017). The active control condition is based on evidence that sleep problems and body dysmorphic disorder symptoms commonly co-occur (Sevilla-Cermeño et al., 2020). Moreover, there is preliminary observational evidence that insomnia has a negative impact on treatment outcomes among individuals with BDD (Sevilla-Cermeño et al., 2020).

This active control condition follows the same structure as the intervention condition. Participants view an approximately five-minute video about how difficulties sleeping can reduce capacity to respond to body dysmorphic disorder symptoms and can intensify distress. The video has a two-step task: 1) to identify areas of sleep hygiene participants can improve, 2) to improve these behaviours. As with the intervention condition, participants will be provided with a short summary of the key points and the task. The schedule of reminders follows the exact same structure as the intervention condition.

3.5.4. Training, supervision and monitoring

All trial personnel have received relevant training, including data privacy and safeguarding and researchers will be further trained in the operation of Doodly, REDCap and the safety procedures.

3.5.4.1. End of the trial

The end of the trial is defined as the point when the final participant has reached the follow-up assessment, which will be no longer than 28 days following baseline.

3.5.4.2. Participant withdrawal from trial

Once a participant has withdrawn from the study, they will not be able to return or re-enter the study. Participants can withdraw from data collection and have their data deleted at any point during the study by emailing the study lead researcher (t.osborn@ucl.ac.uk). After data collection for the entire study has been completed (December 2027), it will not be possible to withdraw from the study. This is because data will be anonymised for either publication or storage or in the public domain. Any participants who withdraw from the study will not be replaced.

3.5.4.3. Discontinuation from the trial

No analyses will be conducted until the final participant reaches the primary endpoint and, therefore, results will not inform decisions to stop the study. Serious adverse events will be monitored. If these occur and there is any indication that these are directly linked to the intervention or control condition itself, consideration will be given to discontinuing the study following consultation with the trial steering committee.

3.5.4.4. Quality control

The conduct of the study will be according to Good Clinical Practice (GCP) principles (European Medicines Agency, 2016). Data quality and safety aspects will be regularly monitored by the trial personnel, who will report to the Trial Steering Committee (TSC). A total of three trial steering group meetings between October 2026 and July 2027 will

be held. The TSC is comprised of a Consultant Clinical Psychologist (Professor Georgina Krebs), the Managing Director of the leading UK BDD charity, the BDD Foundation (Kitty Newman), a lived experience advisor (Daniel Butcher), Senior Research Fellow and Registered Nurse (Dr Tom Osborn), and Consultant Clinical Psychologist (Dr Amita Jassi).

3.5.5. Data management

The study will comply with the General Data Protection Regulation and Good Clinical Practice principles to conduct the study.

3.5.5.1. Data collection and handling

The following data management measures will be implemented to adequately manage and protect data. All personally identifiable data will be kept on UCL's OneDrive/SharePoint server, accessible only to the trial personnel. Personal data will never exit UCL's servers and will never be used in any publication or other form of communication of results. All published results or data will not include any identifiable or personal data.

All participants will be assigned a study ID. To coordinate the study and send emails/text message reminders as part of the intervention and control condition, participants are required to provide personally identifiable information, including emails and phone numbers. This information will remain on REDCap on UCL OneDrive/SharePoint servers. No other personally identifiable information will be collected. For analysis, the study ID will be used for each participant, and personally identifiable information will remain in the REDCap system. Hence, all data outputs, including demographic, mental health measures, and other measures, will be pseudonymised before analysis.

The trial personnel will remain blinded to the group assignment. Blinding will be applied at the level of the REDCap system. Assignment to condition will be automated via the REDCap randomisation module within the REDCap platform. The algorithm will be set before the study start date. The investigators will be able to monitor summary data generated by REDCap, participant progress and completion to enable troubleshooting during the study.

Pseudonymised data from the REDCap platform will be downloaded at the end of the trial, which is defined as the day after the final participant's date of four-week follow-up assessment. In these data, the condition assignment will be coded as either 1 or 2, which is randomly assigned by REDCap. Hence, the trial personnel will remain blinded during the core analysis process. Unblinding to condition will occur once the core analysis process is completed and a draft of the manuscript is agreed.

The code used in the core analysis process will be pre-specified and uploaded onto GitHub before starting the core analysis.

All questionnaires and intervention videos will be held and administered using the REDCap platform. This is a UCL-administered research platform designed for research purposes. It uses key data protection standards. UCL administers and manages access and use of REDCap at the university. Hence, only UCL staff can access REDCap. This study is set up so that only the primary investigators can access this study via the REDCap platform.

All data will be stored on REDCap for the trial component of the study will be stored on REDCap. All qualitative data will be stored on Microsoft Teams, which is part of UCL OneDrive/Sharepoint servers.

4. Statistical analysis

4.1. Statistical principles

4.1.1. Organisation of data and data analyses

The statistical analysis plan will be finalised and approved before commencing core analysis. Analysis code will be prepared and published on GitHub before data collection has completed to reduce risk of bias.

4.1.2. Confidence intervals and p-values

All statistical tests will be two-sided. Two-sided 95% confidence intervals will be presented, and inference on coefficients of interest in regression models will be made based on their respective p-values. For the primary outcome, an alpha = 0.05 will be used.

4.1.3. Adherence to condition

Adherence to the intervention is defined as completion of the measure of the proximal target in the intervention and active control conditions. These targets are engagement in appearance-related behaviours (intervention condition) or engagement with sleep hygiene (control condition).

4.1.4. Analysis populations

The intention-to-treat (ITT) population will include all randomised participants according to the condition they were randomised to receive. The ITT population will necessarily exclude any participants who withdraw, or withdraw permission, from the study.

4.2. Study population

4.2.1. Recruitment and retention

A CONSORT diagram will provide a detailed description of participant numbers at each time point during the study.

4.2.2. Baseline characteristics

A table of the demographic information collected at baseline summarised separately by intervention condition will be presented. All categorical variables will be reported as counts and percentages, whereas continuous variables will be summarised either as means and standard deviations (SD) or medians and interquartile ranges, depending on the distribution of the data.

4.3. Statistical analysis plan

4.3.1. Primary outcome analyses

Primary outcome analysis will follow Vickers' recommendations for the analysis of randomised controlled studies (Vickers & Altman, 2001). The ANCOVA formulation will be implemented in a mixed-effects model, described below.

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

$$\boldsymbol{\vartheta} = \boldsymbol{E}[\boldsymbol{\Upsilon_i}\mathbf{AppearB} - \boldsymbol{\Upsilon_i}\mathbf{SleepH}] \ (\mathbf{1})$$

The contrast of interest is:

$$\mathrm{H}_0\colon \vartheta = 0 \text{ vs. } \mathrm{H}_1\colon \vartheta \neq 0 \ (2)$$

The estimator is:

$$\Upsilon_i, FU = \beta_0 + \beta_1 Intervention_i + \beta_2 \Upsilon_i BL + \varepsilon_i \ (3)$$

Here, Υ_i, FU and $\Upsilon_i \mathrm{BL}$ are the primary outcome at the follow-up of the intervention and the baseline measure before the start of the intervention, respectively. $Intervention_i$ indicates whether the participant is allocated to the intervention or control condition.

The measure of interest is estimated through the coefficient of Intervention.

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

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

4.3.2. Sample Size

The primary analysis is an ANCOVA of the two-week BIQ score by intervention adjusted for the baseline BIQ score.

Sample size calculation assumed: i) standardised between group difference of d=0.40, taken as the difference between within group SMD observed for the intervention in the pilot (d=0.95) and within group SMD reported for a digital sleep intervention on anxiety d=0.55) (Freeman et al., 2017); ii) two-side alpha = 0.05; iii) power 80%; iv) correlation between BIQ at baseline and two week follow up of 0.60, based on the pilot; 30% loss to follow-up at two weeks, as observed in the pilot, mitigated through a prize draw and coffee vouchers.

Sample size was estimated by simulation (5,000 simulations). To detect an SMD of 0.40, a sample size of 133 would have 80% power at the 0.05 alpha level. Accounting for 30% attrition (133 / 0.70), 190 participants will be recruited in total.

4.3.3. Secondary outcome analyses

The effect of the intervention condition on secondary outcomes will be assessed using the same method as the primary outcome. P-values for secondary analyses will not be reported, only confidence intervals.

4.3.4. Exploratory analyses

One analysis will explore whether changes in the appearance-related behaviours mediate between baseline and follow-up measures. This will be implemented by including the mid-intervention appearance-related behaviours in a causal mediation analysis (Imai et al., 2010). This will estimate the average causal mediation effect of appearance-related behaviours, the average direct effect of the intervention condition, the average total effect and the percentage mediated by appearance-related behaviours (Imai et al., 2010).

A second analysis will explore whether adjusting for health service use attenuates or strengthens the treatment estimate in the primary outcome analysis. This will be implemented by including a binary variable of past-month healthcare utilisation in the model.

4.3.5. Missing data

A summary table of withdrawals from the study, loss to follow-up and other missing outcome data by condition assignment will be presented.

Potential bias due to missing data will be investigated by comparing the baseline characteristics of the participants with and without missing values. Depending on the

quantity of missing values, predictors of missingness may be identified. A sensitivity analysis that includes these predictors of missingness as covariates in the primary analysis model will be conducted.

If this missing at random assumption can be justified, multiple imputation may be performed. An imputation model will include all outcome data, baseline demographics, and predictors of missingness, if these can be identified. The primary outcome analysis will then be repeated.

4.3.6. Reporting

All analyses will be reported in accordance with the CONSORT checklist and any particular requirements of targeted academic journals (Moher et al., 2012).

4.4. Objective 1: To evaluate the efficacy of the REFLECT intervention compared to an active control

4.4.1. Summary of baseline data

The CONSORT guidelines will be followed when reporting the study data (Moher et al., 2012). Demographic information collected at baseline will be summarised and presented in a table by intervention condition. All categorical variables will be reported as counts and percentages, whereas continuous variables will be summarised as means and standard deviations. No statistical tests will be conducted to assess baseline differences between intervention conditions (Moher et al., 2012).

4.4.2. Primary outcome analysis plan

The primary outcome analysis will use linear mixed-effects models with restricted maximum likelihood estimation. The model will include a fixed effect for time, intervention condition and the interaction between time and intervention condition and a random intercept for individual. The estimate for the interaction between time and condition will be reported with a confidence interval and p-value. The baseline credibility score will be included as a covariate to adjust for baseline differences in this score.

4.4.3. Analysis of secondary outcomes

The same method described in section 4.4.2 will be used for the secondary outcome, except only confidence intervals will be reported.

4.5. Objective 2 : To evaluate feasibility

Both the rate of recruitment into the trial and the proportions retained in each intervention condition will be used as indicators of feasibility. Rate of recruitment will be calculated as the mean rate of recruitment across all months of the trial, with the target

rate as n=16 (see 3.5.1.1). Retention will be calculated based on the proportion of those randomised in each condition who complete follow-up questionnaires at the endpoint of the study, which is four weeks following baseline. As the intervention is brief, potentially low cost and pilot data demonstrated 70% retention at two weeks, the intervention will be determined as feasible if 70% of participants are retained at two weeks. This corresponds to retention rates observed in similar intervention trials (Patel & Cougle, 2024).

4.6. Objective 3: To evaluate acceptability

A table summarising the means and standard deviations of individual scales of the TFA will be presented. Correlations between each of the individual scales and the acceptability scale will be conducted.

The qualitative data will be analysed using framework analysis (Pope et al., 2000). This is chosen because it was developed for applied research questions and for mixed methods studies, where integration with quantitative findings is anticipated. Analysis will be conducted in accordance with the five steps of framework analysis: familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Pope et al., 2000). Normalization Process Theory (NPT) will be used as the primary thematic framework (May et al., 2022). NPT is a mid-range sociological theory used extensively to analyse implementation processes in feasibility and acceptability studies of health interventions (May et al., 2018).

4.7. Objective 4: To evaluate safety

A table summarising the numbers and proportions of participants who report negative effects from the Negative Effects Questionnaire will be presented (Rozental et al., 2019). Additionally, an increase of 10 points on the BIQ from baseline to follow-up at two or four weeks will be considered an adverse event since this exceeds the threshold for reliable change (National Collaborating Centre for Mental Health, 2018)

4.8. Adverse events

An adverse event (AE) is defined as any adverse occurrence to a participant 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 associated with receiving the intervention.

Each is to be classified by the Principal Investigator as serious or non-serious. An AE is defined as a Serious Adverse Event (SAE) if it:

- Results in death.
- Is life-threatening.

- Requires inpatient hospitalisation or prolongation of existing hospitalisation.
- Results in persistent or significant disability or incapacity.
- Is otherwise considered medically significant by the investigator.

4.8.1. Expected Adverse Events

There is no reason to expect any adverse events because this is a brief intervention and there is no prior literature to suggest otherwise. A previous study of N=75 participants completed a similar intervention to that evaluated in this planned study reported no adverse events (Patel & Cougle, 2024).

4.8.2. Related Adverse Events

All available information will be used to assess if and how an adverse event relates to the administration of the intervention, including the Negative Effects Questionnaire (Rozental et al., 2019). The final decision will be 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 AEs will be categorised in accordance with the definitions below:

- Likely related: Clinical event occurring within a reasonable time after administration of the intervention. It is more likely the event is attributable to the intervention rather than a disease or medication.
- Possibly related: Clinical event occurring within a reasonable time after administration of the intervention. It is plausible the event is attributable to either the intervention or the disease or medication, but we lack sufficient evidence.
- Not related: Clinical event that is not reasonably related to the intervention. It is more likely the event is attributable to the disease or medication rather than the intervention.

4.8.3. Handling of adverse events

Given the nature of the data collection and the short duration of the intervention and trial, assessment of adverse events will be possible in the following ways. Of note, items related to suicide, suicidal ideation/thoughts and thoughts about death or trauma are not included in our questionnaires.

A consultant clinical psychologist (Prof Krebs) is always reachable by the research team to manage any clinical risks arising.

4.8.3.1. Remote sessions for participants

Before the intervention, participants are informed that they can withdraw from the intervention and study at any time. The trial personnel will remotely monitor participant progress through the study, and participants will be able to contact researchers via email should any problems occur. Contact between participants and trial personnel will be recorded using a tick list and open-ended reporting held on UCL OneDrive/SharePoint systems.

4.8.3.2. Participant interviews with a researcher

Before the interview, participants will be reminded that they can stop the interview at any time without giving a reason. None of the interview questions is about distressing topics related to mental health. Topics of discussion will be focused on issues related to acceptability. In the unlikely event participants make a disclosure, the researcher will follow a standard operating procedure to manage and report risk.

For all participants, the following text will be displayed at the end of the data collection sessions (interviews or REDCap data collection) (see Box 1).

Box 1: Resource information for participants

Below are some resources for support. These are provided to all participants regardless of their questionnaire responses. You may wish to take a screenshot of these resources to refer to at any point.

If you are in immediate danger of hurting yourself or others:

- Go directly to the Accident & Emergency (A&E) department of your local hospital.
- Call 999 to request an ambulance if you are unable to reach the hospital yourself.

If you're feeling distressed and need urgent support:

- Contact your GP surgery to request an emergency appointment. If your GP surgery isn't open, call 111 for free out-of-hours NHS medical support.
- Call Samaritans (www.samaritans.org; Tel: 116 123) – a free 24/7 mental health helpline.
- Call Nightline (www.nightline.org.uk; Tel: 0207 631 0101; Email: listening@nightline.org.uk) - a listening service for students, by students. They're available overnight for online chat and calls from 6pm-8am.
- Text SHOUT (www.giveusashout.org; text the word 'Shout' to 85258) - a free 24/7 text messaging service for anyone in the UK who needs support.
- Call SANEline (www.sane.org.uk ; Tel: 0300 304 7000) - a free mental health helpline open between 4pm to 10pm, 365 days a year, serving Great Britain and Northern Ireland.

Additional sources of support:

- Your GP, who is able to able to support you by offering treatments and/ or refer on to other relevant professionals.
- NHS Talking Therapies – you can be referred by your GP or self-refer to your local service online.
- The Body Dysmorphic Disorder Foundation (ww.bddfoundation.org/ Email: support@bddfoundation.org) – UK-based BDD charity.
- Beat Eating Disorders (www.beateatingdisorders.org.uk/; Tel: 0808 801 0677; Email: help@beateatingdisorders.org.uk) - UK leading charity supporting those affected by eating disorders.
- Mind (www.mind.org.uk; Tel: 0300 123 3393) – Mental health charity in England and Wales.

All AEs will be recorded in a specific log (including date and a brief description of the event), which the Principal Investigator will use to evaluate them according to their severity. Should an SAE arise, the investigator will notify the Research Ethics Committee and the Trial Steering Committee (TSC).

4.9. Data sharing

All non-identifiable data will be kept in secure UCL servers and UCL computers with access restricted to the research team. After the study, the anonymised data, which 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.

4.10. Ethical considerations

The risks from the study are expected to be very low for the participants given the mild nature of the intervention. Also, a previous similar intervention showed no evidence of any harm (Patel & Cougle, 2024). The potential benefits to participants and the scientific value of the study far outweigh the potential risks of participation.

As part of the study, special category and personal data will be collected, for which explicit ethical informed consent will be sought. The lawful basis for processing will be "public task" and "research purposes" for special category data.

Participants will complete mental health questionnaires in the screening and study. These questionnaires will only be completed individually, and all items that could be distressing have been removed.

4.11. Implications

The vision is to develop a preventative intervention for people with body dysmorphic disorder symptoms. This intervention needs to be clinically viable, cost-effective, feasible, and acceptable to young people. In addition, the study may discover potential mechanisms that contribute to the development and maintenance of BDD.

4.12. Funding

The study has received funding from the UCL Grand Challenge for Mental Health and Wellbeing Strategic Grant in 2025.

4.13. Publication plans

The trial personnel plan to publish two peer-reviewed papers for academic audiences. One will report on the efficacy, feasibility and acceptability of the intervention in terms of quantitative outcomes. The second will report on the qualitative findings related to acceptability.

In addition, findings will be disseminated to clinical and lay audiences. This includes conferences both internal and external to CUL, lay summaries for universities and BDD charities.

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