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Getting into a good headspace: a study protocol of a pragmatic trial for an eating disorder prevention program in an Australian youth mental health service

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Received: 30 October 2023 / Accepted: 19 February 2024
Published online: 26 February 2024

Abstract
Eating disorders (EDs) are serious, deadly disorders that emerge in adolescence and early adulthood. Further, reported incidences of EDs are increasing worldwide. As such, accessible, affordable, and effective early intervention and prevention efforts are critical. The *Body Project* is a well-established ED prevention program with demonstrated success at reducing ED symptom severity and the risk of onset of EDs in young females. However, it has not yet been formally evaluated in an Australian population, nor have the benefits of the treatment for young people of all genders been thoroughly investigated. This protocol paper outlines the design for a study which aims to investigate the outcomes and feasibility of the *Body Project* as a brief ED prevention program within an Australian youth mental health service: headspace Camperdown. This pragmatic trial will compare outcomes between a *Body Project* treatment group and a *Treatment-as-usual* control group. Primary outcomes include body image concerns, ED symptomatology and general psychological distress, measured pre- and post-treatment, and at one-month follow-up. All young people attending headspace Camperdown for care are eligible for participation in the trial. The *Body Project* program is comprised of four group-based 1.5 h sessions run over 4 consecutive weeks. Overall, a trial of the *Body Project* as an ED prevention program is warranted to investigate the outcomes of the intervention in this sample and will provide valuable information about the feasibility for widespread implementation of the treatment as part of a stepped-care approach to intervention for EDs at youth mental health service locations across Australia. ANZCTR Trial Registration Number: ACTRN12623000695606 (registered 29 June 2023).

Keywords Eating disorders · Early intervention · Prevention · Body image · Clinical trial · Stepped-care

1 Introduction

The impact and prevalence of eating disorders (EDs) has increased significantly worldwide [1–3]. Global lifetime prevalence rates of EDs have been estimated at 8.4% for women and 2.2% for men [2]. EDs are more prevalent in adolescents with 22% of Australian adolescents meeting criteria for an ED diagnosis [3, 4]. Research suggests that ED prevalence rates are 32.9% for girls, 12.8% for boys and 31.3% for adolescents who identified as gender diverse (i.e., they self-reported their gender identity to be a gender 'other' than male or female, examples include non-binary, gender-queer, gender-fluid) [3, 4]. Research has indicated an increase post COVID-19 in ED symptomatology, greater

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concern and preoccupation with food, shape, eating and exercise, and increased associated psychological distress [5, 6]. These increases have been evidenced particularly in younger populations, who report symptoms of disordered eating, including dietary restriction, purging, and shape and weight concerns [7]. Factors that have contributed to these post-COVID increases include changes in daily routine, confinement, exposure to social media use and news coverage and reduced access to health professionals and treatment [5, 8, 9]. Other possible factors include conflict at home, deterioration in friendships and family relationships and increased videoconferencing [10, 11].

EDs are associated with increased risk for adverse physical health conditions, increased psychological distress, functional impairment, and negative impacts on interpersonal relationships [12–14]. Due to the significant physiological and psychological impacts of EDs, EDs are associated with the highest mortality of all the psychological disorders including higher rates of suicidality compared to other conditions [15, 16]. Given the associated severity and mortality of these disorders, it is critical that efforts are made to reduce the incidence of these disorders, particularly in young populations shown to be at risk for onset and where prevalence is high [12, 17, 18]. Research has indicated that the vast majority of individuals with diagnosed EDs do not receive treatment [19], and for those who do remission rates remain modest often with less than half of individuals treated achieving full remission or recovery from the ED at longer term follow-up [20, 21]. Additionally, better longer-term outcomes have been associated with factors such as shorter duration of illness prior to treatment and earlier engagement with intervention [21]. As such, easily accessible, affordable, and effective early intervention and prevention efforts are critical to changing the trajectory of EDs [22]. Prevention efforts involve intervening in response to detected risk factors or prodromal symptomatology, and ideally before a diagnosable disorder has been established [22]. Preventative ED care has a clear clinical rationale (i.e., the ability to reduce and/or mitigate the mental health risk and burden for the individual), but also is important in its ability to reduce financial and public health burden [22].

Although several ED prevention programs have been developed, one has consistently demonstrated efficacy across a range of different settings. The *Body Project* is a well-established, dissonance-based ED prevention program with demonstrated success at reducing ED symptom severity and the risk of onset of EDs [23, 24]. It was developed based on evidence that has established body dissatisfaction and shape/weight concerns as key risk factors for developing clinical EDs, particularly during adolescence [25]. The program was originally designed for young women to perform a variety of tasks in order to critique a 'thin beauty ideal', in order to encourage the reduced pursuit of this ideal, both theoretically and behaviourally [24].

Empirical evidence in support of the *Body Project* has included positive outcomes from multiple research groups, including tests of the intervention theory, efficacy and effectiveness trials, and comparative trials [24]. Meta-analytic data has demonstrated that dissonance-based eating disorder prevention programs (i.e., the *Body Project*) produce significantly larger reductions across various outcomes, including body dissatisfaction, thin ideal internalization, eating disorder symptomatology and negative affect, compared to minimal-intervention control groups [24]. Additionally, the efficacy of the program has been found to be further enhanced when the *Body Project* program takes place over four-to-six sessions, when the program is delivered to groups of approximately 10 young women, and when trained clinicians are implementing the program's group sessions [24].

More recently the *Body Project* program has demonstrated cross-cultural evidence, indicating similar reductions in body image concerns, negative affect, and ED symptomatology across different racial and cultural groups in the United States [26], in young Chinese women [27], young Brazilian women [28], and preliminary evidence for Saudi women [29]. Other recent data has also indicated the potential for peer-led groups, when resource constraints limit clinician-led intervention [30]. Additionally, there is evidence for the efficacy of virtual implementation of the program [31]. This research has been conducted in samples with varying clinical status including a general sample of young women [29], young women at risk of developing an ED [27, 28, 30, 31], and young women who met criteria for threshold and subthreshold EDs [26]. A qualitative review of the existing literature has suggested that since the programs' development, the *Body Project* has reached over 3.5 million young women in over 125 countries globally [23]. Overall, this increasing body of evidence highlights the promise and potential for this brief, time-limited prevention programs under these optimised conditions, and argues for the continued and widespread dissemination of the program and the associated positive outcomes.

This program is yet to be formally implemented and evaluated in an Australian population, nor has its implementation within an existing early intervention service utilising a stepped care approach to treatment been formally assessed. Moreover, existing evidence has predominantly focussed on outcomes for female adolescents and young adults. Few trials have examined the benefits of the program for young males or those with another gender identity (e.g., non-binary, gender-queer, gender-fluid, and others). One pilot randomised control trial has provided preliminary

evidence for reduced body dissatisfaction and eating pathology for men in a mixed-gender modification of the program [32]. It is critical to continue to reduce risk of body image dissatisfaction and development of EDs for all vulnerable individuals. This also means diverging from a sole focus on thin-ideal internalisation when examining body image concerns for young females and beginning to examine more contemporary, societally relevant, and gender-neutral, or diverse-gender inclusive, body image ideals such as the muscular/toned, curvy and androgynous looks that are highly promoted on social media platforms such as Instagram and TikTok.

Consequently, a trial of the *Body Project* as an ED prevention program is warranted to investigate the potential feasibility and outcomes for a sample of young Australians of all genders. This understanding will be valuable to future populations of young people who may then benefit from preventative intervention or early treatment. It may also be effective for those in the community suffering from subclinical or prodromal EDs, and helpful for clinicians working with young populations and subclinical ED populations.

headspace is Australia's national youth mental health initiative, designed to provide early intervention services to young Australians aged 12–25 years, who have mild to moderate mental health symptoms [33]. headspace aims to provide affordable, accessible, specialised and multidisciplinary mental health care to young people and utilises a stepped-care approach to treatment [34, 35]. Since 2006, it has grown to establish more than 150 centres across metropolitan, regional and rural areas of Australia, and has supported more than 770,000 young people [33]. The average duration of care for a young person's first episode of care is 17 weeks (119 ± 111.18 days), with engagement in services consisting of an average of 4.6 treatment sessions (± 4.4 sessions) [36]. The headspace model has been promoted internationally, with countries including Canada, New Zealand, Singapore, and the UK exploring ways to emulate headspace-like integrated models into their own healthcare systems to better address youth mental health [34, 37]. headspace remains the largest international integrated (i.e., offering multidisciplinary services at one location) primary mental healthcare initiative undertaken, and has demonstrated demand for mental health and associated services among young Australians [38, 39]. Recent data has revealed that 47% of young people presenting for care at a headspace centre reported significant body image concerns and over one-third reported engaging in disordered eating behaviours [7]. Therefore, utilising headspace as the study setting for an initial feasibility study for the *Body Project* as an ED prevention program will allow for the many young Australians vulnerable to developing an ED who are currently accessing mental health care at headspace to benefit from the program.

2 Current study

The current study aims to investigate the outcomes, benefits and feasibility of the *Body Project* as a brief evidence-based eating disorder prevention program implemented within an Australian youth mental health service. This non-randomised, pragmatic trial will compare outcomes between two conditions: 1) the *Body Project* treatment group, and 2) a *Treatment-as-usual* control group, in order to examine the effectiveness of the prevention program for reducing body image concerns, eating disorder symptomatology and general psychological distress. Outcomes will be compared pre- and post-treatment and at one-month follow-up. Additionally, both quantitative and qualitative data on the acceptability and feasibility of the intervention as embedded within the service as part of a stepped care model will be collected from headspace service users, including both *Body Project* treatment completers and young people accessing their usual care at headspace, as well as from other key stakeholders including headspace clinicians, professional and administrative staff and members of the centre's youth advisory group.

In accordance with the previously outlined research [23, 24, 32], the following study hypotheses were formed:

H1 Compared to pre-treatment, the *Body Project* treatment group will report reduced body image concerns, ED symptomatology and general psychological distress post-treatment and at one-month follow up.

H2 ompared to the *Treatment-as-usual* control group, the *Body Project* treatment group will report reduced body image concerns and ED symptomatology post-treatment and at one-month follow up.

H3 That an interaction effect will be observed, such that compared to the *Treatment-as-usual* control group, the *Body Project* treatment group will report greater reductions in body image concerns and ED symptomatology between pre-treatment, and both post-treatment and at one-month follow up.

H4 That the *Body Project* treatment intervention will result in positive outcomes (i.e., reduced body image concerns, ED symptomatology and general psychological distress) in males, non-binary and gender diverse young people, as well as in young females.

H5 *H5:* Finally, that the implementation of the *Body Project* treatment intervention within the headspace stepped care service model will be viewed favourably in terms of acceptability and feasibility by the service users and other key service stakeholders.

3 Method

The present study protocol is reported according to the SPIRIT checklist [40]. The study protocol and trial has been approved by the University of Technology Sydney (UTS) Human Research Ethics Review Board (HREC #X23-8405) and has been registered with the Australia New Zealand Clinical Trials Registry (ANZCTR Registration Number: ACTRN12623000695606, registered 29 June 2023).

4 Trial design and setting

This study is a 2 (Treatment) × 3 (Time) non-randomised, pragmatic preference trial to evaluate the effectiveness of the *Body Project* as an ED prevention program in a sample of young people presenting for care at a headspace centre. It will compare study outcomes between two treatment groups, the *Body Project* treatment group versus the *Treatment-as-usual* control group. Data will be collected at three time points; T1 (Pre), T2 (Post), and T3 (one month follow-up).

All study procedures, including recruitment, treatment, and data collection, will be conducted at headspace Camperdown. headspace Camperdown is a large, metropolitan multidisciplinary youth mental health service with a clinical team including psychologists, GPs, a psychiatry registrar, social workers and exercise physiologists. This service is located within the Brain and Mind Centre at the University of Sydney. headspace Camperdown provides approximately 6000 occasions of service to an average 1200 young people per year, half of which are new patients to the centre [41]. The average age of the young people who attend headspace Camperdown for care is 19.3 years (65.9% female) with 3.5% identifying as Aboriginal or Torres Strait Islander, 24.5% as culturally or linguistically diverse (CALD) and 37.8% as LGBTQIA + (lesbian, gay, bisexual, transgender, intersex, queer, asexual and other sexually or gender diverse). A high proportion of young people present as either being sad or depressed (39.9%), or anxious (29.5%), to account for 69.4% of total presentations and comparable with national averages [41].

Recruitment will include a minimum sample of 82 individuals aged 12–25 years. Treatment-as-usual will be utilised as a control condition due to the use of a study setting where individuals are already treatment seeking and maintains other benefits such as controlling for many non-specific therapy factors, and ethical advantages due to not withholding or delaying treatment or care [42]. As this study is taking place in a 'real world' clinical setting, the pragmatic preference trial design was deemed most suitable to reduce burden on the already very busy clinical and professional staff at the service and to make access to care as easy as possible for the real service users making up the participants in this study. Pragmatic trials offer valuable insights into the real-world applicability and effectiveness of treatment interventions and are implemented in such a way as to aim to cause the least amount of disruption to the experience of 'standard' care for the service user [43, 44]. Therefore, as part of this design treatment group allocation will not be randomised or blinded, instead all consenting participants will be invited to attend the treatment group and participants will voluntarily elect themselves to be a part of either study condition. See Fig. 1 for a flowchart of the study design.

5 Participants

Participants will be young people aged 12–25 years presenting at headspace Camperdown, who have the ability and willingness to provide informed consent, participate and comply with the study. No restrictions will be imposed by gender or other demographic characteristics other than the age range eligibility. No additional exclusion criteria will be applied to consenting individuals beyond those already utilised at headspace Camperdown. These pre-existing exclusion criteria include individuals with a disease or psychological illness that would interfere with their ability to understand the requirements of the study and treatment or interfere with the evaluation of the patient's safety and of the study outcome.

An a-priori power analysis was run using G*power [45]. In order to adjust multiple comparisons in the testing procedure, an alpha of 0.05 was adjusted to 0.017 in accordance with the Bonferroni method. An a-priori power of 0.95 was utilised as per the recommended minimum power for planned frequentist analyses, as well as a Cohen's f effect size of 0.2. Using these estimates, a total sample size of 82 participants was required (41 per group). Thus, for our study to achieve the minimum statistical power using these estimates and to manage for potential participant dropout, we aim to recruit 60 participants (ideally aiming for six groups of 10 participants) for the *Body Project* treatment group, and a matched 60 participants for the *treatment-as-usual* control group. This calculation is additionally supported by previous ED trial protocols who obtained similar estimates [46].

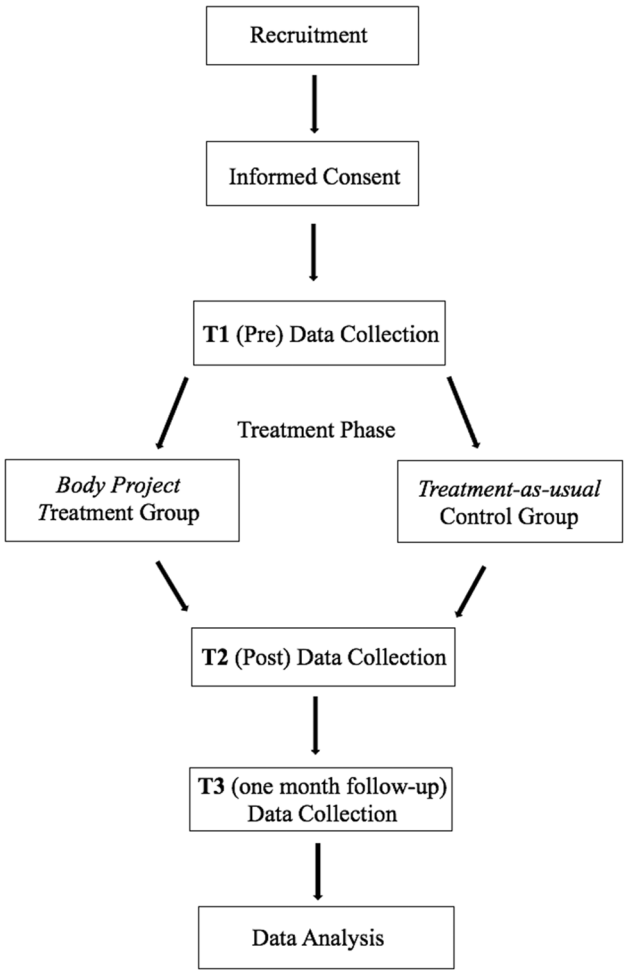

Fig. 1 Flowchart of study design

6 Materials

6.1 Body appreciation scale (BAS-2)

The BAS-2 [47] is a 10-item self-report questionnaire, and is considered a measure of positive body image, examining individuals' acceptance of, and favourable opinions towards and respect for their body (e.g., 'I feel love for my body'). Participants are asked to rate whether the item is true of them on a scale of 1 (*Never)* to 5 (*Always),* where higher scores indicate higher body appreciation. It had demonstrated good psychometric properties cross-culturally [48].

6.2 Depression, anxiety, stress scale (DASS-21)

The DASS-21 is a 21-item self-report questionnaire that examines three related negative emotional states; depression (e.g., 'I felt that life was meaningless'), anxiety (e.g., 'I felt I was close to panic') and stress (e.g., 'I found it hard to wind down') [49]. Participants are asked to rate items according to how much each statement applied to them over the past week on a scale of 0 *(Did not apply to me at all)* to 3 *(Applied to me very much or most of the time)*, where higher scores indicate higher depression, anxiety and stress. It has demonstrated good psychometric properties across cultures [50].

6.3 Eating disorder examination questionnaire short (EDE-QS)

The EDE-QS is a brief, 12-item version of the more commonly used 28-item EDEQ [51], that assesses ED symptomatology and severity in the seven days prior to assessment (e.g., '…Have you had a strong desire to lose weight?'). Ten items are rated on a 4-point scale (*0 days* [0] to *6–7 days* [3]), and two items on a 4-point scale (*Not at all* [0] to *Markedly* [3]), where a higher global score reflects greater frequency and severity of symptoms. The short form was utilised to reduce participant burden. The EDE-QS has been seen to be psychometrically and conceptually sound [51].

6.4 Eating disorder core beliefs questionnaire revised (ED-CBQ-R)

The ED-CBQ-R is a 15-item self-report measure that assesses core beliefs relating to EDs [52]. It contains four subscales, reflecting four dimensions of core beliefs; self-loathing, unassertive/inhibited, demanding/needing help and support, and abandoned/isolated. Items (e.g., 'selfish') are rated on a 7-point scale (*Feels very much untrue* [1] to *Feels very much true* [7]), with higher scores reflecting higher ED core beliefs. The ED-CBQ-R has previously demonstrated good factor structure, internal consistency ($\alpha = 0.73$ to 0.92) and construct validity [52, 53].

6.5 Ideal body stereotype scale revised (IBSS-R*)*

The IBSS-R is a 6-item scale that was originally designed to measure internalization of societally relevant stereotypical female body ideals [54]. Items are rated on a 5-point scale from 1 (*Strongly disagree)* to 5 (*Strongly agree)*, where a higher overall score indicates greater endorsement of ideal-body stereotypes. It has demonstrated good internal consistency and test–retest reliability [54, 55]. For the purposes of this study, the scale and its items were adjusted to reflect more contemporary, relevant and gender inclusive ideal-body stereotypes (e.g., 'People who are "in shape" [fit and strong] are more attractive').

6.6 Inside out screener

The Inside Out Screener is a 6-item novel screening tool utilised for early detection for high risk and early stage eating disorders, developed for both self-referral and use in clinical settings [56]. One item ('How is your relationship with food?) is rated on a 5-point scale from 1 (*Worry and stress free)* to 5 (*Full of worry and stress)*, and the remaining five items (e.g., 'Does your weight, body or shape make you feel bad about yourself?') rated on a 5-point scale from 1 (*Never)* to 5

(*All the time)*. A higher overall score indicates a higher degree of risk. It has shown excellent preliminary evidence for its psychometric properties [56].

6.7 Kessler psychological distress scale (K10)

The K10 is a 10-item scale utilised for measuring general psychological distress [57]. Items (e.g., 'In the past 4 weeks, about how often did you feel tired out for no good reason?') are rated on a scale 5-point scale from 1 (*None of the time)* to 5 (*All of the time*), where a higher score indicates higher distress. It has demonstrated good clinical utility, reliability and validity [58].

6.8 Perceived sociocultural pressure scale (PSPS)

The PSPS is a 10-item scale used for assessing the perceived pressure to be thin individuals have experienced from individuals from friends, family, and the media [54]. Items (e.g., 'I've felt a strong message from the media to have a thin body') are rated on a 5-point scale from 1 (*None)* to 5 (*A lot)*, with higher scores indicating higher perceived sociocultural pressure. It has demonstrated good internal consistency and test–retest reliability [54, 55].

6.9 Questions to assess intervention acceptability and feasibility

A series of questions have been devised by the authors to assess the acceptability of the intervention. Questions to assess acceptability have been informed by the theoretical framework of acceptability (TFA) [59]. According to the TFA, acceptability of healthcare interventions involves seven core components: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy [59]. Item wording has been based on suggestions made by Sekhon et al. (2022) who developed a TFA informed questionnaire to assess acceptability of healthcare interventions [60]. Additional items will assess the feasibility of the intervention as part of the stepped care model implemented at the service. Item wording has been informed by the results of Klaic et al. (2022) who conducted an overview of reviews on implementation of healthcare interventions and reported on the common definitions of 'feasibility' described in these studies (e.g., 'practicality', 'ease of delivery', and 'cost-effectiveness') [61].

7 Procedure

Participants will be recruited via flyers distributed throughout the trial setting (headspace Camperdown). These will invite individuals to participate in the 4 week, four-session *Body Project* program (1.5 h per session), or to participate by completing questionnaires at the required time points if they participate in the *Treatment-as-usual* control group. Interested participants will be presented with a participant information statement and consent form to provide informed consent to participate in the study. As part of enrolment, consenting participants will self-allocate to a treatment condition. At this time, participants will receive a unique enrolment number which will be utilised on all study materials and questionnaires. Informed parental consent will be sought for any participants under-age participants. Any participants 16 years or under will require written informed consent from their parent or legal guardian to be provided to finalise enrolment in the study. After informed consent has been provided, participants will complete the T1 [pre-treatment] questionnaire. Questionnaire data will be collected via online self-report using Qualtrics Survey Software. This test battery includes collecting demographic information and all outcome measures outlined in the materials section. Demographic information collected includes age, gender identity, ethnicity, and about current (if any) mental health diagnosis(es). Participants are also asked they have experienced an eating disorder either currently or in the past but have not spoken to a health professional about it in order to obtain a diagnosis.

Intervention will commence after enrolment and allocation procedures have been finalised. Detailed information about the intervention and control conditions have been outlined in the subsequent intervention section. Participants will be closely monitored and assessed for safety and adverse events throughout the entire study period. After the fourth visit to headspace Camperdown to close intervention period, participants will complete the T2 (post-treatment) questionnaire (identical to T1 but without demographic information). One month after the T2 questionnaire has been completed, all participants will be asked to complete the T3 (one-month follow-up) questionnaire. After

Table 1 Schedule of enrolment, interventions and assessment in accordance with SPIRIT guidelines

Timepoint	Study period					
	Enrolment	Post-allocation/intervention				Close-out
	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4	
	T1 [Pre]				T2 [Post]	T3 [one-month follow-up]
Enrolment						
Eligibility	✓					
Allocation	✓					
Informed consent	✓					
Interventions						
Body Project treatment group		✓	✓	✓	✓	
Treatment-as-usual control group		✓	✓	✓	✓	
Assessments						
Demographics	✓					
Adverse event & serious adverse event assessment	✓	✓	✓	✓	✓	✓
Body appreciation scale (BAS-2)	✓				✓	✓
Depression, anxiety, stress scale (DASS-21)	✓				✓	✓
Eating disorder examination questionnaire short (EDE-QS)	✓				✓	✓
Eating disorder core beliefs questionnaire revised (ED-CBQ-R)	✓				✓	✓
Ideal body stereotype scale revised (IBSS-R)	✓				✓	✓
Inside out screener	✓				✓	✓
Kessler psychological distress scale (K10)	✓				✓	✓
Perceived sociocultural pressure scale (PSPS)	✓				✓	✓

the close of the study period and data collection is complete, data analysis will be carried out by the chief and co-investigators. Table 1 displays the schedule of enrolment, interventions and assessment in accordance with SPIRIT guidelines.

8 Intervention

8.1 Body project treatment

The *Body Project* treatment program is a cognitive dissonance-based body acceptance intervention [62]. It is a manualised intervention that consists of four group sessions and was originally designed to help adolescent girls and young women resist sociocultural pressures to conform to the thin beauty-ideal and reduce their pursuit of thinness through written, verbal and behavioural exercises. For our treatment groups, the program will be comprised of four group-based 1.5 h sessions, running over 4 consecutive weeks. It contains a variety of key principles and tasks summarised in Table 2. For the purposes of utilising this treatment in an inclusive group of gender diverse individuals, some of the content of sessions were adapted to include and reflect other relevant body ideals (e.g., thin ideal, curvy ideal, fit ideal, muscular ideal). A clinical psychology trainee will lead group-sessions based on the treatment manual.

Table 2 Overview of body project group session content

Session	Focus	Key principles and tasks
Session 1	Introduction & psychoeducation	▪ Introduction and welcome ▪ Psychoeducation about definitions of body ideals ▪ Discussion of origins of body ideals (e.g., thin ideal, curvy ideal, fit ideal, muscular ideal) ▪ Participants write letter to younger selves discussing costs ▪ Self-affirmation task recording positive aspects of the self
Session 2	Cognitive challenging	▪ Discuss reflections from two tasks from Session 1 ▪ Opposing attitudes role play to try to dissuade the facilitator from pursuing body ideals ▪ Identify examples of experiences of pressure to conform to body ideals ▪ Verbally challenge pressures and identify strategies to resist this
Session 3	Motivation & behavioural experiments	▪ Review exercises from Session 2 ▪ Challenge statements in support of body ideals made by peers through role play ▪ Discuss motivations for participating in the program ▪ Create behavioural experiments to challenge body ideal concerns ▪ Discuss body activism ideas
Session 4	Review & summary	▪ Review outcomes of behavioural experiments ▪ Discuss experiences with body activism ▪ Review subtle ways body ideals are perpetuated ▪ Write second letter to younger self to support and self-affirm

The content of the group sessions was adapted from the *Body Project* manual, to include the key focus, principles and tasks, but to include psychoeducation, challenging, and behavioural experiments targeting varied relevant body ideals (Stice, E., Rohde, P., & Shaw, H. [2012]. *The Body Project: A Dissonance-Based Eating Disorder Prevention Intervention [2 edn]*. Oxford Clinical Psychology. https://doi.org/10.1093/med:psych/9780199859245.001.0001)

8.2 Treatment-as-usual control

Participants in the control group will continue to attend headspace Camperdown sessions with their usual clinician/s over the 4 consecutive week period.

9 Data analysis strategy

Statistical analyses will be carried out using IBM Statistical Package for Social Sciences (SPSS) Statistics (version 26.0) predictive analytics software. Preliminary and descriptive analyses will be conducted to examine general sample characteristics and other variable information. This includes analyses such as examining distribution of data to assess for violations of normality assumptions for all variables, floor and ceiling effects, examining the internal consistency of measures using McDonald's Omega (Ω), and the relationships between variables using Kendall's Tau correlations.

To investigate the treatment outcomes and test research hypotheses, *F*-tests (two-way analysis of variance [ANOVA]) will be conducted to investigate differences in repeated measures within groups (between T1, T2, and T3), and between group differences (between groups effects at T2 [post-treatment] and T3 [one-month follow-up]), and finally to examine the interaction between conditions (time and treatment). Additionally, baseline differences between groups for outcome measures will be examined pre-treatment (T1), and may be used as a covariate. These differences will be examined for all outcome measures (measures of body image, ED symptomatology and general psychological distress). An alpha of 0.05 for testing statistical significance may be adjusted in accordance with the Bonferroni method to allow for multiple comparisons.

Several additional analyses will be considered if they contribute to a more nuanced understanding of study outcomes and assist in the overall interpretation of findings. This includes examining the impact of demographic variables on outcomes using *t*-tests and chi-square tests, and subsequently utilising these variables as covariates or moderators. Due to the use of 'forced response' items in the online test battery, we do not anticipate any missed data.

10 Ethical considerations, data and risk managsecseement

Informed consent will be obtained by providing participants with a Participant Information Statement and obtaining written informed consent. Parents of under-age participants will also receive a Participant Information Statement and will provide informed consent. Under the TGA CTN Scheme, all data from intervention studies conducted will be kept indefinitely. However, all information will be treated confidentially. All data will be de-identified by the researchers, and only the approved researchers will have access to the de-identified data. All recruitment, data collection and intervention will be supervised by senior clinical psychologists. If participants wish to withdraw from the study once it has started, they can do so at any time without having to give a reason, by contacting the chief-investigator. Data will be stored on a secured server and managed by the approved study investigators.

In the case of an unexpected medical emergency or workplace accident/injury, the WHS policy of headspace Camperdown and UTS will be followed regarding the reporting of incidents. A distress protocol has been created in order support any distressed participants, both during and after the intervention. As the study and intervention are occurring within the participants treatment centre (headspace Camperdown), their treating clinicians and senior clinical staff will be on site to assist with distress. Any instances of negative or adverse outcomes will also be included in trial reports.

11 Discussion

With an early age of onset and high comorbidity with anxiety and mood disorders, young people experiencing mental health distress are especially at risk of developing an ED [7]. Body image concerns, prodromal disordered eating, and clinical eating disorders (EDs) have a significant impact on the physical and psychological wellbeing of individuals as

well as significant societal costs [12–14]. Easily accessible, affordable, and effective early intervention and prevention efforts are critical to changing the trajectory of these serious and often fatal conditions. There is a need for effective ED prevention programs suitable for individuals of all gender identities that can be widely disseminated to those vulnerable to developing an eating disorder.

This paper has outlined the protocol for a unique trial of the *Body Project* dissonance-based eating disorder (ED) prevention program in an Australian youth mental health setting. The aim of this project is to investigate the benefits and feasibility of offering a brief evidence-based ED prevention program within an existing early intervention service (headspace centre). It is hoped that this program will demonstrate efficacy as an early intervention strategy which can be readily implemented in settings like headspace centres and other services and settings where young people access mental health support.

Recent research has found that young Australians presenting at a headspace centre for general mental health support are reporting high rates of body image concerns and disordered eating symptoms [7]. As Australia's National Youth Mental Health Foundation with over 150 youth-friendly mental health services across Australia, headspace centres are uniquely placed to offer an accessible early intervention for EDs to those most vulnerable to developing an ED. Therefore, an increased understanding of the feasibility and outcomes of the *Body Project* as an ED early intervention program in this type of service could inform and influence future stepped care service delivery models to include preventative intervention or early treatment as part of standard practice. This will benefit future populations of vulnerable young people (such as those suffering from subclinical or prodromal EDs) who, without access to an early intervention such as the *Body Project,* would go on to develop an eating disorder.

Acknowledgements We acknowledge the Gadigal and the Wangal peoples of the Eora nation, upon who's ancestral lands this research was conducted. We pay our utmost respect to Elders past and present. The authors acknowledge the staff and young people of headspace Camperdown (the trial site) for their willingness to be involved with this study. The authors acknowledge the University of Technology Sydney Faculty of Health for funding this research.

Author contributions AB obtained funding for the trial and is the lead investigator and trial coordinator. AH is the research project manager, SB is the psychologist responsible for implementation of treatment sessions at the trial site, and BH is the trial site coordinator. AB conceived and designed the study. Material preparation was performed by AB and AH, and data collection coordinated by SB and BH. AH prepared the first draft of the trial protocol which included assisting with refining the study design and data analysis plan in collaboration with AB. AH prepared the first draft of this manuscript, subsequent versions were refined in collaboration with AB, SB and BH. All authors read and approved the final manuscript.

Funding The study is supported by funding from a University of Technology Sydney (UTS) Faculty of Health "ADRSF Research Engagement Grant". This funding was obtained and is being managed by Amy Burton.

Data availability The datasets used and/or analysed during the current study are available from the corresponding author on request.

Declarations

Ethics approval and consent to participate This study was approved by the University of Technology Sydney (UTS) Human Research Ethics Committee (HREC: HREC #X23-8405). All procedures performed in studies involving human participants are in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All participants were provided with a participant information statement and provided their informed consent to participate in the study. All participants read a Participant Information Statement allowing them to make an informed choice as to whether they wanted to participate in the research or not. They were informed that they could also cease participation at any stage with no penalty to them or to their relationship with headspace or UTS. For any underage participants, informed consent was obtained from the parents/legal guardians of participants who are under 16 years. The ethics of the consent procedure was approved as above.

Competing interests The authors declare no conflicts of interest. There are no relevant financial or non-financial competing interests to report or benefits that have arisen from this research.

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