

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

PROTOCOL TITLE:

Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

LEAD RESEARCHERS:

Stephanie Budge, PhD
Professor, Department of Counseling Psychology
University of Wisconsin-Madison

Louis Lindley, M.A.
Doctoral Candidate, Department of Counseling Psychology
University of Wisconsin-Madison

Table of Contents

1.0	Study Summary.....	2
2.0	Background.....	3
3.0	Study Objectives and Endpoints.....	4
4.0	Number of Participants.....	5
5.0	Inclusion and Exclusion Criteria.....	5
6.0	Special Populations.....	6
7.0	Recruitment Methods.....	7
8.0	Consent/Assent Process.....	8
9.0	Process to Document Consent in Writing.....	9
10.0	Setting.....	9
11.0	Study Intervention.....	10
12.0	Study Timelines.....	10
13.0	Procedures Involved.....	11
14.0	Comparison of usual care and study procedures.....	13
15.0	Withdrawal of Participants.....	13
16.0	Data Management and Confidentiality.....	13
17.0	Provisions to Protect the Privacy Interests of Participants.....	15
18.0	Sharing of Results.....	16
19.0	Data and Specimen Banking.....	16
20.0	Study Analysis.....	16
21.0	Potential Benefits to Participants.....	17
22.0	Risks to Participants.....	17
23.0	Provisions to Monitor the Data to Ensure the Safety of Participants.....	19
24.0	Economic Burden to Participants.....	19
25.0	Resources Available	19
26.0	Multi-Site Research.....	20
27.0	References.....	20
28.0	Appendices.....	23

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

1.0 Study Summary

Study Title	Trans Care Teen Intervention
Brief Summary	The current project aims to enhance the well-being of transgender and nonbinary (TNB) youth (ages 13–17) by adapting an online intervention, Trans Care, to specifically address their needs. This adaptation began with a focus group of diverse TNB youth to gather feedback on the relevance, applicability, and feasibility of the Trans Care Teen intervention. Their insights will inform modifications to ensure the intervention is developmentally appropriate and accessible. Following these revisions, Trans Care Teen will be evaluated in a randomized controlled trial (RCT) to assess its efficacy in reducing gender dysphoria symptoms, increasing active coping, and improving overall well-being.
Number of study sites	1
Study Design	Randomized controlled trial.
Primary Objective	Development and testing of the Trans Care Teen webapp.
Secondary Objective(s)	A pilot randomized controlled trial (RCT) of Trans Care Teen’s efficacy.
Research Intervention(s)/ Investigational Agent(s)	Trans Care Teen webapp, an educational and interactive website designed to improve coping strategies of TNB youth ages 13-17.
Drugs/devices used on study (including any IND/IDE #)	N/A
Study Population	TNB youth aged 13-17.
Sample Size	The RCT will utilize a sample of 346 TNB youth.
Study Duration for individual participants	We anticipate it will take participants between 4 – 5 hours to complete Trans Care Teen intervention. However, participants can exit and reengage the webapp over a one-month period.
Study Specific Abbreviations/ Definitions	TNB (trans and nonbinary) RCT (randomized controlled trial)

2.0 Background

2.1 Trans and nonbinary (TNB) youth, those whose gender identity differs from their sex assigned at birth, can experience a unique form of distress called gender dysphoria (GD). Gender dysphoria is an experience of distress or discomfort when an individual's gender identity is different than what is expected based upon their sex assigned at birth (Coleman et al., 2022). In the literature, the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5-TR diagnosis of GD and the experience of GD are often used interchangeably, leading to confusion about the distinction between the two (Byne et al., 2018; Davy & Toze, 2018). To clarify this distinction, we adopt a community-informed understanding of GD in this protocol. This approach recognizes gender dysphoria as a set of experiences related to the distress caused by a mismatch between an individual's affirmed gender and assigned sex/gender, which can vary in intensity both within and across individuals (Galupo et al., 2020; Lindley & Galupo, 2020). Therefore, when we refer to GD, we are not referring to the formal DSM diagnosis of GD.

The impacts of GD are felt on both an individual and community level. At the individual level, studies have indicated that youth with higher levels of GD experience increased anxiety, depression, and nonsuicidal self-injury (Mason et al., 2023). Most crucially, youth who experience GD are at an extreme risk for suicidal ideation and attempts (Marconi et al., 2023). At the community level, completed suicide by individuals who experience GD can have long standing impacts on their family, friends, and local TNB community through increased depression symptoms (dickey & Budge, 2020). Further, current legislative efforts across the United States have either attempted to or have successfully outlawed TNB youth from accessing medical care show to significantly reduce GD symptoms and suicidality (Tordoff et al., 2022). Fortunately, psychotherapy has been identified as an effective means of helping TNB individuals respond to GD (American Psychological Association, 2015; Budge et al., 2021); however, there are barriers for TNB youth in accessing therapy, such as: financial (Benson, 2013), geographical (Reisner et al., 2022), discriminatory (Hunt, 2014), and inadequacy of care (Morris et al., 2020).

In response to these barriers, online interventions are identified as effective alternatives to traditional psychotherapy (Harrer et al., 2019; Sevilla-Llewellyn-Jones et al., 2018; Spijkerman et al., 2016). Web-based interventions are self-guided programs operated via online websites that prescribe a specific course of educational information (Barak et al., 2009). The content of these interventions is most frequently based on existing theories of psychological change, such as cognitive behavioral therapy (CBT; Martinengo et al., 2021) or dialectical behavioral therapy (DBT; Vasiljevic et al., 2022). The skill building aspects of CBT and DBT are presented as web-page modules where participants learn how to integrate and utilize them for their specific problem(s).

2.2 Our recent work developing the Trans Care Intervention (TCI), a self-guided online program, has created a freely accessible avenue for integrating psychological care. The TCI is the only tested psychological intervention specifically designed to reduce gender dysphoria. It equips transgender and

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

nonbinary (TNB) individuals with coping strategies to improve well-being and alleviate gender dysphoria symptoms. A pilot feasibility and acceptability study demonstrated significant reductions in depression, stress, and gender dysphoria (Lindley & Budge, Under Review). These promising findings suggest that adapting the TCI to address the unique developmental needs of TNB youth could further expand its impact.

2.3 The TCI comprises one introduction and seven interactive modules that span psychoeducation on GD and coping, training of specific coping interventions, and the development of a personalized coping plan. These modules draw upon the translational coping research of Lindley and Budge (2022) who, identified the specific and unique coping strategies of TNB individuals to develop and validate the Trans and Nonbinary Coping Measure. These TNB-specific coping strategies serve as the basis of the intervention modules while also drawing upon results of qualitative studies in which TNB individuals described their personal ways of coping with GD (e.g., Lindley et al., 2023) and best practices derived from existing online TNB and general coping interventions. Further, the TCI utilizes coping skills training from CBT and DBT to help participants identify which coping skills will be most effective for their experience of GD (Edraki et al., 2018; Linehan, 2015; Roos et al., 2020). The current project will incorporate input from experts in adolescent gender dysphoria treatment and a focus group of TNB youth to refine and adapt the TCI into a tailored intervention for TNB adolescents—Trans Care Teen Intervention (TCTI).

3.0 Study Objectives and Endpoints

3.1 The overall purpose of this project is to adapt the TCI to be developmentally appropriate and accessible to TNB youth ages 13-17 and to create a free intervention that can be disseminated widely throughout TNB communities to improve well-being in an easy, accessible way. Development and execution of the TCTI involves two primary aims:

- 1) Focus group of TNB youth to understand its applicability in meeting their needs.
- 2) A pilot randomized controlled trial (RCT) of TCTI's efficacy.

Aim 1 involved gathering qualitative feedback from TNB youth regarding the content of the TCTI intervention modules, acceptability of content, clarity of language, cultural relevance, accessibility of the online format, engagement with interactive components, and perceived usefulness of coping strategies for managing gender dysphoria. Their feedback guided refinements to ensure the intervention was developmentally appropriate, affirming, and effective for TNB adolescents prior to conducting a RCT.

Aim 2 involves an RCT to compare psychological well-being and coping strategy outcomes between participants in the TCTI intervention and a waitlist control group. An intent-to-treat analysis will be conducted to assess the effectiveness of the intervention, accounting for all participants as randomized regardless of adherence. Finally, waitlisted participants will be offered the intervention within one month of the completion of data collection.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

3.2

Hypothesis 1 (causal, maps onto Aim 2)

H1a: TNB Participants who received the TCTI will demonstrate improvement on quantitative measures of psychological well-being, GD symptoms, and coping strategies compared to waitlisted youth.

H1b: Changes will be maintained at 3 months follow-up indicating that the TCTI has a sustained impact on improving TNB youths' well-being.

3.3 The primary endpoint of this study will be to determine if participants who engaged the TCTI experienced psychological improvement in their mental health as a result of completing the intervention.

3.4 There are no safety endpoints included as part of this study.

4.0 Number of Participants

4.1 We will recruit a sample of 346 TNB youth for the RCT (173 in the intervention group and 173 in the waitlist/control group). Intentional recruitment efforts will be employed for both to target rural participants and TNB youth of color to ensure the generalizability of our results.

4.2 The sample size for the RCT study was determined by a priori power analyses. We will do our best to recruit 346 participants for the RCT. There may be a situation in which we do not enroll as many participants as we are projecting, but we are confident in our recruitment processes. We will only screen and enroll the number of participants noted. If participants withdraw early (see note below), we will enroll additional participants only to achieve the anticipated sample.

4.3 Participants will be informed that their participation in the RCT is completely voluntary and that they may withdraw from the study at any time. If participants withdraw from the RCT prior to completing at least the first two modules, they will be replaced with a participant from the screening pool until 173 participants in the intervention group have completed at least the first two TCTI modules.

5.0 Inclusion and Exclusion Criteria

5.1 Interested participants in the RCT study will first engage an online screening survey that will assess eligibility across the following domains:

1. At least 13 and no older than 17 years of age.
2. Identify as transgender, transsexual, nonbinary, and/or have a transgender history.
3. Experience gender dysphoria.
4. Time available to commit to completing a 6–8 hour online intervention within one month and 1-2 hours to complete follow up surveys over 4 months.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

Participants who do not meet eligibility requirements for the RCT study will be sent to the end of the survey and will not be asked for any identifiable information. Further, their responses will not be saved. Data from eligible participants who are not enrolled in the RCT will be maintained until the last participant is enrolled in the RCT. This is to account for any participant attrition and to allow for the enrolling of additional eligible participants to either study. Only study team personnel will receive the identifiable data which will be maintained on a HIPAA compliant secure UW ResearchDrive. Risks of breach of confidentiality will be minimized by keeping the screener survey separate from any other data and only approved study personnel will have access to the ResearchDrive containing the screener survey responses.

Eligible participants will provide basic demographic information (i.e., birthdate, race, sexuality, gender identity, rurality, SES) and be prompted to provide an email address email address to send study reminders (i.e., to fill out surveys or complete TCTI modules). No other identifiable information will be retained.

5.2 The final study sample will include individuals who aligned with the screening criteria above. Eligible participants from the screener survey will be placed in either the intervention or waitlist/control group through a stratified by gender randomization. Then eligible participants in each group will be provided with a random number, with the 20 lowest random numbers from each group enrolled in the study. This enrollment process will repeat until 173 participants in the intervention group have completed at least the first two TCTI modules.

5.3 General exclusion guidelines for study include: (1) under 13 years old, (2) over 17 years old, (3) individual does not identify as transgender, transsexual, nonbinary, and/or have a transgender history, (4) does not experience gender dysphoria, (5) is unable to commit to the time requirements of the RCT study, (6) residing outside of the US, (7) does not receive guardian consent, or (8) do not have access to an internet connected device.

5.4 Priority enrollment will be given to rural and TNB youth of color if the study samples begin to become predominantly (i.e., greater than 70%) comprised of white and urban TNB participants to ensure generalizability of findings.

6.0 Special Populations

6.1

Children/Minors (HRP-416 - CHECKLIST - Children)

We are enrolling transgender and nonbinary (TNB) youth ages 13-17 to evaluate whether the adaptation of the TCI is appropriate and effective in reducing gender dysphoria and psychological distress while improving adaptive coping strategies for this population.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

Inclusion of this age group is critical to ensure that the TCTI meets the developmental and mental health needs of TNB adolescents.

To protect participants' rights and welfare, we have implemented several safeguards. We will obtain consent from at least one guardian or parent and ensure that they are fully informed of the study's requirements, including potential risks and benefits. Further, we will obtain youth assent to ensure they are equally informed of risks and benefits to participation. Additionally, we have collaborated with experts in adolescent gender dysphoria and mental health to ensure that the intervention is evidence-based, developmentally appropriate, and unlikely to cause harm. These measures will help safeguard participants while allowing us to assess the intervention's effectiveness in supporting TNB youth.

This study is considered minimal risk, given that engaging in the modules poses no greater risk than the degree or likelihood of harm a youth would face during everyday life or during a psychological exam. And, given that the initial results of the RCT of these modules with TNB adults indicate that there was minimal discomfort and significant psychological improvement, it is reasonable to infer that the benefits outweigh any minimal risks of discomfort.

7.0 Recruitment Methods

7.1 We will engage a nationwide sample of TNB participants by posting the recruitment flyer and recruitment email or script on social media groups (e.g., Facebook, Reddit) that support TNB individuals. We will also have community organizations, hospitals, and medical centers across the country who have adolescent gender identity clinics share these materials on our behalf (see section 7.3 for details).

7.2 Potential participants will self-identify in response to recruitment flyers, emails, and word of mouth from other participants.

7.3 Recruitment for the RCT will take place in March of 2026. The recruitment flyer and script will be posted by the study team to publicly accessible social media websites (e.g., Facebook, Instagram, Reddit) that support TNB youth. We will follow the guidelines provided in the Investigator Manual including that responders may not contact the study team through private messaging on social media and any posts to specific groups on social media will adhere to the groups' administrative rules. Additionally, we will send our recruitment flyer and script to TNB focused youth organizations and gender identity clinics across the United States and request that they share them on our behalf.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

7.4 A recruitment flyer and script will be utilized to recruit participants. This information is included in the application.

7.5 All participants who participate in the RCT study will be compensated for their participation. To assist 173 participants in the intervention group of the RCT study in completing at least two modules of the TCTI, incremental compensation is provided for completion of each module. The introduction module provides \$1, the first \$4, the second \$6, the third \$9, the fourth \$13, the fifth \$18, the sixth \$22, and the seventh \$27 for a total of \$100 for completing all modules (i.e., approximately \$20/hour). Participants are given four weeks to complete all modules, any modules completed after the four-week period will not receive compensation. Participants are provided with a suggested schedule within the webapp as well as automated email and/or text message reminders to ensure they are able to complete all modules within four weeks.

Participants in both the intervention and waitlist/control group are provided \$5 for completing baseline survey measures, \$5 for post intervention measures, and \$10 for completing 3-month follow up measures. Participants in the waitlist/control group are provided \$20 in compensation if they complete all three rounds of surveys (see section 13.1). As such, participants in the intervention group can receive up to \$120 and waitlist/control participants can receive up to \$40 for participation.

Compensation for the RCT study will be provided within one week of the closing of the study (i.e., after the last participant has completed the three month follow up measures). RCT participants who leave the study early will be provided compensation for the parts of the study they completed. Compensation will be provided via gift cards, mobile payment services (e.g., Venmo, PayPal, CashApp, etc.), or cash.

8.0 Consent/Assent Process

8.3 Guardian/parental consent will be provided for the RCT studies via an online form containing the informed consent document as well as a question instructing guardians/parents to provide a unique research key for their minor (i.e., *your child's favorite color followed by their favorite food and then the first number of your address and the first letter of your street address*). They will be asked to write down the unique code to be able to provide it to their child for the child to provide assent and have the consent/assent linked. We have requested to waive signed consent because obtaining a signature is impracticable in an online environment. Instead, guardians/parents will be provided a "click here" button for online consent. Guardians/parents who do not consent will be taken to a page that thanks them for their interest and notifies them that their child does not meet inclusion criteria. Guardians/parents who do consent will be provided with a link to a survey where youth can provide assent. There is a waiting period between guardians/parents indicating consent and their child being enrolled into the study due to the need to additionally receive assent from the youth.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

The guardian/parent consent document that will be included in the online form is uploaded as part of the IRB application.

We are seeking consent from only one guardian/parent due to the study being minimal risk.

Given the focus of the current study is on TNB youth aged 13-17, all participants are considered minors/children, and we will not be enrolling anyone who is not a minor at the start of the study. Further, as part of the screener survey participants will provide their birthdate and any participant younger than 13 or 18 or older will not be enrolled as they do not meet inclusion criteria. Further, if a youth turns 18 during the course of the study, they will be asked to provide consent to participate.

All youth will indicate their assent to participate in the RCT studies via an online screening survey. The link to the screening survey will be provided to guardians/parents to share with their child after they provide consent. Youth in the online surveys will be provided a “click here” button for online assent, because obtaining a signature is impracticable in an online environment. The assent information for inclusion of the studies will be included as the last page of the online screening survey. As part of the screening survey, participants will be asked to provide the unique research key their guardian/parent created to link their assent to consent. There is a waiting period between participants indicating assent and enrollment into the study given the need to link guardian/parental consent to youth assent. The assent document that will be included in the online survey is uploaded as part of the IRB application.

9.0 Process to Document Consent in Writing

9.2 There is minimal risk involved with the current studies and engagement with the intervention. The study is minimal risk and involves no activities that would normally require written consent outside the research context. This study is considered minimal risk, given that engaging in the modules poses no greater risk than the degree or likelihood of harm a youth would face during everyday life or during a psychological exam. And, given that the initial results of the RCT of these modules with TNB adults indicate that there was minimal discomfort and significant psychological improvement, it is reasonable to infer that the benefits outweigh any minimal risks of discomfort. Prior to the screening survey, study participants will be informed that there will be documentation linking them to the research (i.e., their email address or mailing addresses [if provided]) should they decide to participate in one or both of the following: 1) enrollment in the intervention, 2) monetary compensation for engaging with some or all of the intervention modules; 3) completion of some or all of the survey measurements. The consent document is included with the IRB application.

10.0 Setting

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

10.1 The RCT will occur remotely as the Trans Care Teen intervention is a webapp and thus is hosted on the internet with no geographical limitations.

11.0 Study Intervention

11.1 The TCTI webapp intervention involves one introduction and 7 interactive modules that are navigated via an online website. The TCTI is designed to help individuals who experience symptoms of gender dysphoria cope with the distress and to encourage a healthy lifestyle. The TCTI is not designed to diagnose, cure, or prevent the DSM-5-TR diagnosis of gender dysphoria (APA, 2022; see Section 1.0). Further, the TCTI webapp functions to provide all users with general patient education to facilitate access to coping strategies. As such, the TCTI is not a medical device nor a diagnostic tool (see Section 520(o)(1)(B) of the FD&C Act).

Participants are initially presented a video with TNB-identified actors describing the TCTI, including what to expect during the intervention, the anticipated completion time, a brief description of each module, and an introductory deep breathing exercise participants can use if they experience elevated mental health distress while engaging with the modules. Module One provides psychoeducation about gender dysphoria (GD) and common triggers (i.e., events or thoughts) that amplify GD symptoms. Participants are then prompted to write common triggers to their GD so they can begin to think about how to cope with these antecedents through avoidance. Module Two introduces the psychological concept of externalization (Carr, 1998), in which TNB-identified actors will describe how thinking about GD as an external force can assist in reducing the impact of GD on their mental health. Participants are invited to draw and upload a picture of their GD to visualize the experience as external to them (Huston, 2021). Module Three provides psychoeducation regarding how to notice what level of gender dysphoria participants are experiencing (i.e., minimal to severe) and introduces mindfulness-based coping skills identified by Lindley and Budge (2022) as having a profound impact on TNB individuals' facilitative coping with intense experiences of GD. TNB actors will demonstrate how to utilize strategies such as deep breathing, sensory grounding, and checking in with needs. Modules Four and Five present examples of action (i.e., attending to the problem or altering the environment that is causing GD) and avoidant (i.e., distancing oneself from the experience of GD or from thinking about GD) coping strategies. They will be demonstrated both visually and descriptively using findings from our previous research (Lindley & Budge, 2022; Lindley et al., 2022). Additionally, participants are invited to write-in other coping strategies they currently use. Participants then engage in an interactive activity in which they will rank the various coping strategies from least to most likely to use. Module Six provides examples of which coping skills are most effective for different triggers of GD to provide participants with an understanding of when to use which coping skills. Finally, Module Seven provides a brief review of what participants learned and an individualized coping plan based upon participants' previous rank ordering of coping strategies. Participants will be able to download this coping "cheat sheet" so that they may return to it when they experience symptoms of GD.

12.0 Study Timelines

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

12.1 The enrollment period for the RCT is expected to take place between March and July of 2026. We anticipate it taking up to five months to enroll participants in the RCT given the need to enroll participants on a rolling basis due to attrition. Participants’ participation will last up to four months although the actual time completing study tasks is estimated to be between 6-8 hours. We anticipate our analysis of the RCT results to be completed by October 2026.

13.0 Procedures Involved

13.1 The RCT study is a causal study of the impact of the TCTI on improving coping skills of TNB youth to reduce symptoms of GD. Participants will be enrolled to the study on a rolling basis. Participants will be randomly assigned to the intervention or waitlist/control group from the screener survey using a stratified race randomization procedure. Once in the two groups, a second randomization will occur by providing each participant a random number. Participants whose random numbers represent the lowest values will be enrolled in the study. Once enrolled in the RCT study, all participants will complete baseline (i.e., pre-intervention) measures of psychological well-being. Next, participants in the TCTI intervention group will complete the modules of the intervention over a four-week period, followed by a re-administration of the measures of psychological well-being five weeks post registering an account of the TCTI website. Participants in the intervention group will receive automatic reminders from the TCTI to complete modules. Participants in the control group will be re-administered the measures of psychological well-being five weeks after their initial administration. Lastly, all participants will be readministered the measures of psychological well-being 3 months after the completion of the last round of administration.

13.2 Schedule of study procedures.

Study Phase	Guardian/ Parent Form	Screener Survey	Baseline	Completion	Follow Up
RCT Study					
Informed Consent	X				
Informed Assent		X			
Demographic Questionnaire		X			
Expanded Demographics			X		
Survey Battery ^a			X	X	X

^aSurvey measures will include: *The Gender Congruence and Life Satisfaction Scale for Transgender and Gender-Diverse Youth (GCLS-Y; Jones et al., 2024)*; a revised for youth version of the *Multidimensional Gender Dysphoria Measure (MGDM; Galupo et al., 2025)*; a revised version of the *Gender Dysphoria Triggers Scale (Goldbach & Knutson, 2023)*; the *Depression, Anxiety, and Stress Scale-Youth (DASS-Y; Szabo & Lovibond, 2022)*; the *Gender Minority Stress and Resilience Measure – Adolescent (GMSRM-A; Schurman et al., 2019)*; a revised for youth version of the *Trans and Nonbinary Coping Measure (TNCM; Lindley & Budge, 2022)*; custom Externalization

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

Measure; custom Mindful Awareness Measure; custom Radical Acceptance measure based on modified items from the Cognitive and Affective Mindfulness Scale- Revised (CAMS-R; Feldman et al., 2007); custom Cognitive Reframe Measure based on modified items from the Competencies of Cognitive Therapy Scale Self Report (CCTS-SR; Buss et al., 2021); custom Gender Affirmation and Euphoria Measure; custom Passive and Active Distraction Measure based on modified items of the Pain Response Inventory for Children – Distract/Ignore subscale (Walker et al., 1997).

13.3 Research procedures for the RCT study will involve the following:

- 1) An initial online form where parents provide consent for the child to participate and create a unique research key (see Section 16.2).
- 2) A screening survey where eligibility is determined through questions about inclusion criteria and demographics, after which potential participants provide assent to participate in the study
- 3) Upon enrollment, participants will be randomly assigned to either the waitlist/control or intervention group.
- 4) All enrolled participants will complete an expanded demographics survey which collects information regarding experiences with gender affirming care, mental health therapy, social transition, and native language.
- 5) Participants in the intervention group will self-administer survey battery measures via Qualtrics. Participants will take the same battery of survey measures at baseline, five weeks after registering an account on the TCTI website. Participants in the waitlist/control group will self-administer survey battery measures completed via Qualtrics. Participants will take the same battery of survey measures at baseline, five weeks post baseline administration, and 3-months post baseline.

13.4 Survey measures for the RCT include:

- The Gender Congruence and Life Satisfaction Scale for Transgender and Gender-Diverse Youth (GCLS-Y; Jones et al., 2024)
- A revised for youth version of the Multidimensional Gender Dysphoria Measure (MGDM; Galupo et al., 2025)
- A revised version of the Gender Dysphoria Triggers Scale (Goldbach & Knutson, 2023)
- The Depression, Anxiety, and Stress Scale-Youth (DASS-Y; Szabo & Lovibond, 2022)
- The Gender Minority Stress and Resilience Measure – Adolescent (GMSRM-A; Schurman et al., 2019)
- A revised for youth version of the Trans and Nonbinary Coping Measure (TNCM; Lindley & Budge, 2022)
- Custom Externalization Measure
- Custom Mindful Awareness Measure
- Custom Radical Acceptance measure based on modified items from the Cognitive and Affective Mindfulness Scale- Revised (CAMS-R; Feldman et al., 2007)

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

- Custom Cognitive Reframe Measure based on modified items from the Competencies of Cognitive Therapy Scale Self Report (CCTS-SR; Buss et al., 2021)
- Custom Gender Affirmation and Euphoria Measure
- Custom Passive and Active Distraction Measure based on modified items of the Pain Response Inventory for Children – Distract/Ignore subscale (Walker et al., 1997).

14.0 Comparison of usual care and study procedures

14.1 Participants can engage in any kind of alternative care or treatment they prefer for their mental health and wellbeing. For example, if they are in psychotherapy or want to seek psychotherapy, they are welcome to. The design of this study does not preclude participants from using therapy. There are not factors that influence the treatments the patient receives.

14.2 There is no standard practice or standard of care for this participant population related to coping.

14.3 Since the intervention is to assist with coping, there are no follow up interventions. There will be follow up surveys, but these assessments are separate from the intervention.

14.4 See above. Participants can engage in any other kind of treatment they prefer while on the waitlist or in the intervention group. They are not proscribed from any treatment while in the intervention or waitlist group.

15.0 Withdrawal of Participants

15.1 It is unlikely that participants will be withdrawn. If a participant is abusive toward study staff, they will be withdrawn from the study. Additionally, any participants who stop taking the intervention but want to re-engage with the intervention after data collection is over will be unable to participate.

15.2 Some participants may choose to end their participation in the study for any reason. We will consider participants who do so as having withdrawn from the study.

15.3 Any participants who choose to withdraw early from the study may request that their data already collected not be used in the study. Participants who complete at least two intervention modules but withdraw from the study will be contacted to complete a re-administration of baseline measures of psychological well-being at five weeks and again at three months post registering on the TCTI website unless they also withdraw consent from follow-up contact.

16.0 Data Management and Confidentiality

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

16.1 Participants will be asked to share their email for enrollment during the screener survey which will be maintained in a separate Qualtrics survey from baseline and follow-up surveys. Additionally, to register an account on the TCTI website, participants must enter their email address. Participants assigned to the intervention group will be given the option to voluntarily provide a mobile telephone number during registration on the TCTI website to receive automated reminder messages via text message. Text message reminders will be used to prompt engagement with the intervention (e.g., reminders to return to the website or complete modules) and will be sent no more than six times per week. Participant's mobile telephone numbers will be stored within the TCTI website separate from the rest of their study data.

Automated study-related text message reminders will be administered using a secure, third-party messaging infrastructure. An automation plugin (Uncanny Automator) will be used to create predefined workflows that link participant activity on the intervention website (hosted on the LearnDash platform) with the delivery of automated text message reminders. These workflows will be limited to administrative functions (e.g., triggering reminder messages based on intervention engagement) and will not involve manual review of individual participant behavior.

Text messages will be delivered through a third-party short message service (SMS) provider (Twilio). Twilio will be used solely to transmit automated reminder messages to participants who have voluntarily provided a mobile telephone number and opted to receive such messages. Message content will be limited to brief reminders (e.g., prompts to return to the intervention website) and will not include sensitive personal information.

Participants will be informed that automated messaging involves third-party service providers and that confidentiality cannot be fully guaranteed for text message communications. Provision of a mobile telephone number is entirely optional. Participants who choose not to provide a telephone number or who decline to receive text message reminders will not be excluded from the study and may fully participate in all study procedures.

Participants who elect to receive text message reminders may opt out at any time by following the instructions provided in the message (e.g., replying "STOP") or by discontinuing participation in the intervention.

At the end of the baseline survey in the RCT study, participants will be asked if they prefer compensation via a gift card or cash. Participants will be notified that to receive cash they must provide a current mailing address and that if they are uncomfortable with providing this information, they should opt for a gift card. Participants who opt for cash will be redirected to a separate survey to provide a mailing address to receive the cash. This cash survey will be stored separately from other data. Additionally, participant's responses to baseline and follow-up measures will be kept separate from any identifying information. The only information linking the participants' screener survey to baseline and follow-up measures or the cash survey will be their research key (see Section 16.2).

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

For data security - everything will be stored on a HIPAA compliant UW ResearchDrive. The information stored within the webapp (i.e., email address and optional mobile telephone number) was subject to cyber security review by a UW-Madison Information Security Risk Analyst.

16.2 Data will be coded, and the “key” linking identities to codes will be kept separately from the data.

- To link participants with repeated assessments, compensation, webapp activities, and email address participants’ guardians/parents will be asked to create a unique, but unidentifiable code (e.g., your favorite color followed by your favorite food, then the first number of your address and the first letter of your street address) to share with their child.

16.3 Other software option that will be stored on departmental server. *Specify the department:* Department of Counseling Psychology, School of Education

16.4 The unique key identified by participants will be destroyed at study closure or at the time of publication.

16.6 To ensure the transparency of our results, the de-identified data and R code from the RCT study will be published with Open Science Federation following the completion of data analysis. Additionally, we may use RCT participants data for secondary research questions. If additional studies occur with the data in the future, additional IRB protocols will be written and submitted with the studies in mind. Thus, all personnel who have access to the data will be IRB-trained and will be included on the approved IRB protocols. Future research will only be limited to the information that is provided in quantitative data.

17.0 Provisions to Protect the Privacy Interests of Participants

17.1 If any of the following apply, check the box for convenience:

- Procedures will be performed in a private area where others cannot see the procedures being performed or overhear the conversation between subjects and researchers.
- All members of the study team are up to date on their institutional HIPAA training.

Participants can engage the intervention and surveys from anywhere they desire.

17.2 Participation in this study will necessitate disclosure of sensitive information, given that participants identify as a TNB youth. Because this intervention is intended for this specific population, it is necessary to determine potential participants’ eligibility for the study.

17.3 Efforts to put participants at ease will occur upon enrollment. We anticipate that participants will feel at ease with the research because study procedures will be carefully explained at the beginning and participants will have the opportunity to ask researchers any questions prior to beginning the intervention. We will also use the Transgender Research Informed Consent (TRICON) Disclosure Policy (see <https://transpolicyreform.wordpress.com/2022/>)

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

[10/08/transgender-research-informed-consent-tricon-disclosure-policy-2022-update/](#)), which provides background information about the researchers and purpose of the study to build trust with communities. Finally, our focus group and experts provided feedback on the questions we will ask during the RCT.

18.0 Sharing of Results

18.1 The data do not meet criteria for reporting clinically relevant information to clients. None of the assessments that we are providing include clinical cutoffs for psychological diagnoses, thus we will not have any diagnoses to present to clients.

18.2 Study results will be disseminated with the public through: 1) empirical articles in scientific journals, 2) conference presentations, 3) local and national community groups, 4) popular press (e.g., zines, infographics, etc.), and 5) promotional videos for the intervention. The study is pre-registered with the International Standard Registered Clinical/social sTudy Number (ISRCTN) clinical trials registration at: <https://www.isrctn.com/ISRCTN11106371>

19.0 Data and Specimen Banking

This project does involve the banking of data for future use. Data from participants who meet eligibility criteria but are not enrolled will be maintained until the last participant is enrolled in the RCT at which point it will be deleted (see Section 5.1). All study data from enrolled participants will be maintained for a period of 7 years post-closing of the study in accordance with the UW-Madison Research Data and Records Schedule #1649. The data will be maintained on a HIPAA compliant UW ResearchDrive only accessible by research study personnel. Data from participants who do not meet eligibility criteria will not be saved.

20.0 Study Analysis

20.1 Hypothesis 1a and 1b will be tested no sooner than three months after the final participant completes the TCTI. Intent to treat, superiority comparisons will be conducted to determine if individuals who completed the TCTI had greater reductions to gender dysphoria and improved coping compared to the waitlist/control group.

20.2 Hypotheses 2. An a-priori power analysis was conducted to determine an adequate sample size for conducting linear mixed models (LMM). With a minimal effect size of .35, alpha of .05, power of .90, two groups, and 3 measurement time points the minimal sample size is 346. The recruitment study accounts for participant drop out such that rolling enrollment will take place until 173 participants in the intervention group complete at least two TCTI modules. We will utilize an intent to treat analyses and all participants who complete baseline measures and at least two modules will be included in the analyses.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

20.3 Participants in the RCT will be randomly assigned to either the intervention or waitlist/control group. These two subsamples will then be compared to each other in LMM.

20.4 Hypotheses 1a and 1b will be tested using linear mixed models (LMM) to examine whether individuals in the treatment group show reduced gender dysphoria and psychological distress and increased coping compared to the waitlist/control group, and whether these effects are sustained over time. Specifically, for Hypothesis 1a, we expect the LMM to reveal greater reductions in gender dysphoria and psychological distress and increases in coping from pre- to post-intervention in the treatment group relative to the waitlist/control group; for Hypothesis 1b, we expect these improvements to be maintained from post-intervention to 3-month follow-up.

20.5 Data from the RCT study will be preliminarily assessed by Louis Lindley once 50 participants have completed the final module of the TCTI. If results indicate that the intervention is likely increasing psychological distress or gender dysphoria (i.e., DASS-Y, GCLS-Y, or MGDM scores increase significantly) the RCT study will be suspended.

20.6 Given that LMM can accommodate missing outcome data under the assumption that data are missing at random (MAR), we will not impute missing outcome values.

21.0 Potential Benefits to Participants

21.1 Past research regarding queer and TNB focused online interventions have found effect sizes of 0.40-1.01 for reducing psychological distress. Additionally, our pilot feasibility and acceptability analyses of the Trans Care intervention demonstrated medium effect size reductions in gender dysphoria, depression, and stress (Lindley & Budge, under review). Given these findings, we anticipate that participants in the RCT study will experience the same benefits observed in the adult version of TCI. We expect changes as a result of the RCT to be sustained for at least 3 months.

22.0 Risks to Participants

22.1 Potential risks for participation include:

- There is the risk of a breach of confidentiality for participants who elect to provide their email address or mailing address for gift card or cash compensation. There is also the risk of a breach of confidentiality for TNB youth who elect to provide their email address to be enrolled in the studies.
- There is the risk of a breach of confidentiality for participants who voluntarily elect to receive automated text message reminders. Text messaging is not a fully secure form of communication, and confidentiality could be compromised if another individual has access to the participant's mobile device (e.g., shared devices, message previews). To minimize this risk, text messages will be limited to brief reminders and

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

will not include sensitive personal information. Participation in text messaging is optional and may be discontinued at any time without penalty.

- There is the risk that participants might be slightly upset by aspects of the research. Participants will encounter scale items and prompts related to experiences with gender related stress and their coping responses. This might cause mild distress for participants who are sensitive to discussing gender related stress. In response, participants are provided the information to three crisis lines specific to TNB individuals in at the beginning of each round of surveys to utilize if they experience increased distress: a) the Trans Lifeline, b) Q chat space, and c) the Trevor Project. However, the intervention is designed to decrease this distress, and a grounding exercise is provided on the first page of the intervention to help combat this risk.

- There is the risk that participants may reveal personal, sensitive, or identifiable information if they elect to provide their email address in the survey, particularly if their email address contains identifiable information (e.g., full name). Any identifiable information that is not an email or mailing address will be immediately deleted. All email or mailing addresses from the RCT studies will be deleted within one month of the conclusion of the study.

- There is the risk that participants may become fatigued or frustrated due to the length of the studies.

- The TCI webapp platform has undergone a cyber security review by a UW-Madison Information Security Risk Analyst to ensure all data retained in the webapp (i.e., email, mobile telephone number, research ID, responses to interactive activities) are secured.

-There is a risk that participants could be “outed” as trans in the event of a data breach. Given that youth have to identify as transgender, transsexual, nonbinary, and/or have a transgender history to participate, it is likely that most participants will already be out to friends and family (e.g., HRC, 2023; Mousavi et al., 2024), and therefore this risk could potentially affect a small portion of the sample. In the event that a youth was not out and gets outed because of their participation in this study, they could face psychological distress and discrimination. This could affect their relationships with friends and family, as well as damage their reputation, given the current political climate. However, they will have access to the support resources provided as part of the study and study staff will also be available to provide additional resources.

22.6 Any participant in the study may withdraw from participating in the research at any time in the research process. Participants may also elect to not participate in certain components of the study for any reason (e.g., if they are experiencing psychological distress due to the process). Participants will be reminded regularly that their participation in the research study is voluntary.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

23.0 Provisions to Monitor the Data to Ensure the Safety of Participants

23.1 The potential harm of the intervention will be assessed at several points. First, content experts will review a draft of the content of the intervention prior to webapp development to ensure that it meets the needs of all TNB youth and is likely to result in increased psychological well-being. Second, feedback from the focus group was integrated into the TCTI to ensure it meets their needs and is affirming of their experiences. Finally, data from the RCT study will be preliminarily assessed by Louis Lindley once 50 participants have completed the final module of the TCTI. If results indicate that the intervention is likely increasing psychological distress (i.e., DASS-Y, GCLS-Y, or MGDM scores increase significantly) the RCT study will be suspended.

24.0 Economic Burden to Participants

24.1 Access to the TCTI is provided at no cost to participants. To access the intervention, study participants are recommended to have access to a desktop computer, laptop, tablet, or smartphone with updated software and Internet connection.

25.0 Resources Available

Will the research be conducted outside School of Medicine and Public Health or UW Hospitals and Clinics (e.g. the researcher does not have an SMPH research feasibility attestation for this study)?	X YES (complete 25.1) <input type="checkbox"/> NO (remove text below, but retain this section)
---	---

25.1 Because this is a nationwide study, we are not concerned about finding the appropriate number of participants. Further, the TCTI is provided for free and represents the only existing free therapeutic intervention for youth who experience gender dysphoria, thus increasing the likely desire of participants to participate in the studies.

The researchers have time carved out for their academic appointments to complete the research procedures. We anticipate that data collection will take approximately 1.5 years for both studies. We anticipate that it will take an additional 6 months to analyze and disseminate all the data.

The researchers all have offices on campus and in their homes to conduct any research procedures. They all have computers and access to the internet. These are the only components that are needed from a facilities perspective.

All research staff are adequately trained to complete all study procedures. Research staff engage in bi-weekly meetings to ensure that communication is clear and consistent throughout the trial.

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

26.0 Multi-Site Research

26.1 N/A

27.0 References

- American Psychiatric Association. (2022). Diagnostic and statistical manual of mental disorders (DSM-5-TR). American Psychiatric Pub.
- American Psychological Association. (2015). Guidelines for psychological practice with transgender and gender nonconforming people. *American Psychologist*, 70(9), 832–864. <https://doi.org/10.1037/a0039906>
- Barak, A., Klein, B., & Proudfoot, J. G. (2009). Defining internet-supported therapeutic interventions. *Annals of Behavioral Medicine*, 38(1), 4–17. <https://doi.org/10.1007/s12160-009-9130-7>
- Benson, K. E. (2013). Seeking support: Transgender client experiences with mental health services. *Journal of Feminist Family Therapy*, 25(1), 17–40. <https://doi.org/10.1080/08952833.2013.755081>
- Brodzinsky, D. M., Elias, M. J., Steiger, C., Simon, J., Gill, M., & Hitt, J. C. (1992). Coping scale for children and youth: Scale development and validation. *Journal of Applied Developmental Psychology*, 13(2), 195–214. [https://doi.org/10.1016/0193-3973\(92\)90029-H](https://doi.org/10.1016/0193-3973(92)90029-H)
- Budge, S. L., Sinnard, M. T., & Hoyt, W. T. (2021). Longitudinal effects of psychotherapy with transgender and nonbinary clients: A randomized controlled pilot trial. *Psychotherapy*, 58(1), 1–11. <https://doi.org/10.1037/pst0000310>
- Carr, A. (1998). Michael White's narrative therapy. *Contemporary Family Therapy*, 20(4), 485–503. <https://doi.org/10.1023/A:1021680116584>
- Clark, L. (2009). Focus Group Research With Children and Youth. *Journal for Specialists in Pediatric Nursing*, 14(2), 152–154. <https://doi.org/10.1111/j.1744-6155.2009.00187.x>
- Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., de Vries, A. L. C., Deutsch, M. B., Ettner, R., Fraser, L., Goodman, M., Green, J., Hancock, A. B., Johnson, T. W., Karasic, D. H., Knudson, G. A., Leibowitz, S. F., Meyer-Bahlburg, H. F. L., Monstrey, S. J., Motmans, J., Nahata, L., ... Arcelus, J. (2022). Standards of care for the health of transgender and gender diverse people, Version 8. *International Journal of Transgender Health*, 23(sup1), S1–S259. <https://doi.org/10.1080/26895269.2022.2100644>
- dickey, lore m., & Budge, S. L. (2020). Suicide and the transgender experience: A public health crisis. *American Psychologist*, 75, 380–390. <https://doi.org/10.1037/amp0000619>
- Edraki, M., Rambod, M., & Molazem, Z. (2018). The Effect of Coping Skills Training on Depression, Anxiety, Stress, and Self-Efficacy in Adolescents with Diabetes: A Randomized Controlled Trial. *International Journal of Community Based Nursing and Midwifery*, 6(4), 324–333.
- Galupo, M.P., Lindley L., & Clements, Z. (In Revision). *Development and psychometric evaluation of the Multidimensional Gender Dysphoria Measure*. American Psychologist.
- Harrer, M., Adam, S. H., Baumeister, H., Cuijpers, P., Karyotaki, E., Auerbach, R. P., Kessler, R. C., Bruffaerts, R., Berking, M., & Ebert, D. D. (2019). Internet

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

- interventions for mental health in university students: A systematic review and meta-analysis. *International Journal of Methods in Psychiatric Research*, 28(2), e1759. <https://doi.org/10.1002/mpr.1759>
- Hunt, J. (2014). An initial study of transgender people's experiences of seeking and receiving counselling or psychotherapy in the UK. *Counselling and Psychotherapy Research*, 14(4), 288–296. <https://doi.org/10.1080/14733145.2013.838597>
- Huston, E. (2021). *Beyond the dominant paradigm: Integrating expressive arts therapy and narrative therapy to best serve the needs of trans and gender non-conforming people: a literature review* [Masters, Lesley University]. https://digitalcommons.lesley.edu/expressive_theses/417
- Jones, B. A., Nguyen, Alisha. L., Sequeira, G. M., Morrison, S. D., & Cahill, L. (2024). The gender congruence and life satisfaction scale for transgender and gender-diverse youth (GCLS-Y): A validation study with samples from the UK and US. *International Journal of Transgender Health*, 1–15. <https://doi.org/10.1080/26895269.2024.2397720>
- Lindley, L. & Budge, S. L. (2022). Development and validation of the Trans and Nonbinary Coping Measure (TNCM): A measure of trans and nonbinary specific ways of coping with gender-related stress. *Psychology of Sexual Orientation and Gender Diversity*, 11(3), 425–441. <https://doi.org/10.1037/sgd0000618>
- Lindley, L. & Budge, S.L. (Under Review). *Piloting an online intervention for gender dysphoria: Feasibility and acceptability of the Trans Care Intervention*. American Psychologist.
- Lindley, L., Pulice-Farrow, L., & Budge, S. (2023). The antecedents of gender dysphoria and the associated thoughts, emotions, and ways of coping: A qualitative analysis and clinical implications. *Counselling Psychology Quarterly*, 36(4), 592–614. <https://doi.org/10.1080/09515070.2022.2142201>
- Linehan, M. (2015). *DBT skills training manual* (2nd ed.). Guilford Publications.
- Marconi, E., Monti, L., Marfoli, A., Kotzalidis, G. D., Janiri, D., Cianfriglia, C., Moriconi, F., Costa, S., Veredice, C., Sani, G., & Chieffo, D. P. R. (2023). A systematic review on gender dysphoria in adolescents and young adults: Focus on suicidal and self-harming ideation and behaviours. *Child and Adolescent Psychiatry and Mental Health*, 17(1), 110. <https://doi.org/10.1186/s13034-023-00654-3>
- Martinengo, L., Stona, A.-C., Griva, K., Dazzan, P., Pariante, C. M., Wangenheim, F. von, & Car, J. (2021). Self-guided cognitive behavioral therapy apps for depression: Systematic assessment of features, functionality, and congruence with evidence. *Journal of Medical Internet Research*, 23(7), e27619. <https://doi.org/10.2196/27619>
- Mason, A., Crowe, E., Haragan, B., Smith, S., & Kyriakou, A. (2023). Gender Dysphoria in Young People: A Model of Chronic Stress. *Hormone Research in Paediatrics*, 96(1), 54–65. <https://doi.org/10.1159/000520361>
- Morris, E. R., Lindley, L., & Galupo, M. P. (2020). “Better issues to focus on”: Transgender microaggressions as ethical violations in therapy. *The Counseling Psychologist*, 48(6), 883–915. <https://doi.org/10.1177/0011000020924391>

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

- Reisner, S. L., Benyishay, M., Stott, B., Vedilago, V., Almazan, A., & Keuroghlian, A. S. (2022). Gender-affirming mental health care access and utilization among rural transgender and gender diverse adults in five Northeastern U.S. states. *Transgender Health, 7*(3), 219–229. <https://doi.org/10.1089/trgh.2021.0010>
- Roos, C. R., Carroll, K. M., Nich, C., Frankforter, T., & Kiluk, B. D. (2020). Short- and long-term changes in substance-related coping as mediators of in-person and computerized CBT for alcohol and drug use disorders. *Drug and Alcohol Dependence, 212*, 108044. <https://doi.org/10.1016/j.drugalcdep.2020.108044>
- Schurman, J. V., Chen, D., Edwards-Leeper, L., Stancin, T., Tishelman, A., Hidalgo, M. A., Petras, H., Chen, D., & Chodzen, G. (2019). The Gender Minority Stress and Resilience Measure: Psychometric validity of an adolescent extension. *Clinical Practice in Pediatric Psychology, 7*(3), 278–290. <https://doi.org/10.1037/cpp0000297>
- Sevilla-Llewellyn-Jones, J., Santesteban-Echarri, O., Pryor, I., McGorry, P., & Alvarez-Jimenez, M. (2018). Web-Based Mindfulness Interventions for Mental Health Treatment: Systematic Review and Meta-Analysis. *JMIR Mental Health, 5*(3), e10278. <https://doi.org/10.2196/10278>
- Spijkerman, M. P. J., Pots, W. T. M., & Bohlmeijer, E. T. (2016). Effectiveness of online mindfulness-based interventions in improving mental health: A review and meta-analysis of randomised controlled trials. *Clinical Psychology Review, 45*, 102–114. <https://doi.org/10.1016/j.cpr.2016.03.009>
- Szabo, M., & Lovibond, P. F. (2022). Development and psychometric properties of the DASS-Youth (DASS-Y): An extension of the Depression Anxiety Stress Scales (DASS) to adolescents and children. *Frontiers in Psychology, 13*, 1–16. <https://doi.org/10.3389/fpsyg.2022.766890>
- Tordoff, D. M., Wanta, J. W., Collin, A., Stepney, C., Inwards-Breland, D. J., & Ahrens, K. (2022). Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. *JAMA Network Open, 5*(2), e220978. <https://doi.org/10.1001/jamanetworkopen.2022.0978>
- Vasiljevic, S., Isaksson, M., Wolf-Arehult, M., Öster, C., Ramklint, M., & Isaksson, J. (2022). Brief internet-delivered skills training based on DBT for adults with borderline personality disorder – a feasibility study. *Nordic Journal of Psychiatry, 77*(1), 1–10. <https://doi.org/10.1080/08039488.2022.2055791>

28.0 Appendices

Provide any additional information relevant to management of the study, such as instructions for specialized procedures, charts or workflow diagrams.

Table 1. *Strategic Activities.*

Objective	Task	Outcome Measures	Timeline
Development of Trans Youth Content	Elicit Feedback from Content Experts	Qualitative feedback from expert consultants regarding adequacy of coverage, language use, and meaningful inclusion of multiply marginalized TNB individuals	March – April 2025
	Integration of Feedback		April – May 2025
Focus Group for the Trans Care Teen Intervention	Recruitment	Qualitative feedback from TNB youth regarding the content of the Trans Care Teen intervention modules, acceptability of content, clarity of language, cultural relevance, accessibility of the online format, engagement with interactive components, and perceived usefulness of coping strategies for managing gender dysphoria.	May – June 2025
	Conduct Groups		July 2025
	Integrate Changes		July – August 2025
Randomized Control Trial (RCT)	Web App Development	The Gender Congruence and Life Satisfaction Scale for Transgender and Gender-Diverse Youth (GCLS-Y; Jones et al., 2024), a revised for youth version of the Multidimensional Gender Dysphoria Measure (MGDM; Galupo et al., 2025), a revised version of the Gender Dysphoria Triggers Scale (Goldbach & Knutson, 2023), The Depression, Anxiety, and Stress Scale-Youth (DASS-Y; Szabo & Lovibond, 2022), The Gender Minority Stress and Resilience Measure – Adolescent (GMSRM-A; Schurman et al., 2019), a revised for youth version of the Trans and Nonbinary Coping Measure (TNCM; Lindley & Budge, 2022), custom items specific to externalization, custom items specific to mindful awareness coping, custom items specific to avoiding physical gender dysphoria triggers, three items form a modified Cognitive and	July 2025 – Feb. 2026
	Recruitment		March 2026
	Enrollment		March 2026 – July 2026
	Analyses		July – August 2026
	Data Dissemination		August – Oct. 2026

PROTOCOL TITLE: Trans Care Teen: Adapting an online intervention to reduce symptoms of gender dysphoria for youth

Affective Mindfulness Scale- Revised (CAMS-R; Feldman et al., 2007), nine items from a modified Competencies of Cognitive Therapy Scale Self Report (CCTS-SR; Buss et al., 2021), the Gender Euphoria Scale (GES; Blacklock et al., 2025), and a modified version of the Pain Response Inventory for Children – Distract/Ignore subscale (Walker et al., 1997).
