BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-076511
Article Type:	Protocol
Date Submitted by the Author:	09-Jun-2023
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Keywords:	Adolescent, Transgender Persons, Depression & mood disorders < PSYCHIATRY, Anxiety disorders < PSYCHIATRY, Feasibility Studies

Protocol for the evaluation of a co-designed group cognitive behavioural therapy intervention for trans young people (TAG TEAM): a feasibility and pilot trial

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ABSTRACT

Introduction: Trans young people are at a higher risk of mental health difficulties such as depression, anxiety and suicidality than their cisgender peers, due in part to their experiences of minority stress. This protocol describes a feasibility and pilot trial of a co-designed group cognitive behavioural therapy (CBT) intervention for trans young people, named Trans Adolescent Group ThErapy for Alleviating Minority stress (TAG TEAM).

Methods and analysis: To evaluate TAG TEAM, we will conduct separate feasibility and pilot trials with trans young people aged 14-16 years who have been referred to the Royal Children's Hospital Gender Service (RCHGS) in Melbourne, Australia. In the feasibility trial, participants will be randomised to either in-person or online intervention arms. Participants will be assessed at baseline and post-treatment, with a nested qualitative evaluation post-treatment. Primary outcomes are the feasibility and acceptability of the intervention and the study design and associated procedures, including comparison of the in-person and online delivery modes. In the pilot trial, participants will be randomised to an intervention or waitlist control arm, with delivery mode determined by the feasibility trial. Participants will complete assessments at baseline, post-treatment and 3 month follow-up. Primary outcomes are the feasibility and acceptability of the randomised controlled trial study design. In both trials, participants will complete assessments related to mood, anxiety, suicidality, quality of life, minority stress, family support and social transition. Quantitative data will be analysed using descriptive statistics. Qualitative data will be analysed using thematic and interpretive analysis.

Ethics and dissemination: The Royal Children's Hospital Human Research Ethics Committee has approved this study (#91162). Findings will inform the development of a randomised controlled trial to evaluate the efficacy of TAG TEAM, and will be disseminated through conferences and peer reviewed journals.

Trial registration number: Feasibility: ACTRN12623000302651. Pilot: ACTRN12623000318684.

ARTICLE SUMMARY

Strengths and limitations of this study

- To our knowledge, this is the first study trialling a CBT intervention addressing minority stress developed with and for trans young people specifically, and the first to use participatory research methods to involve trans young people in the development and evaluation of such an intervention.
- TAG TEAM is based on the needs and preferences of trans young people and centres on themes related to minority stress and CBT principles.
- The feasibility and pilot trial study design will allow us to assess and improve TAG TEAM before proceeding to a full-scale randomised controlled trial (RCT).
- The feasibility trial's small sample size may limit external validity.
- The feasibility and pilot trials will recruit from a clinical population of trans young people referred to a paediatric gender service, and this may limit generalisability to other populations.

INTRODUCTION

Transgender and gender diverse (hereafter trans) are terms used to describe people whose gender is different from the sex assigned to them at birth. Trans young people are at high risk of mental health conditions such as anxiety, depression and suicidality.[1–3] This poor mental health is in part associated with the abuse, rejection and discrimination that trans young people frequently experience in broader society.[1–3] These experiences are referred to as minority stressors,[4] and are theorised to contribute to psychological distress in gender diverse people through engendering self-blame, self-hate and low self-esteem.[5] For example, a study of 859 trans young people found high rates of adverse experiences such as peer rejection (89.0%), bullying (74.0%) and discrimination (68.9%), and noted that these experiences were associated with depression, suicidality and anxiety.[6]

In addition, many trans young people's mental health is adversely affected by gender dysphoria, which is distress associated with an incongruence between gender and sex assigned at birth. To help address this dysphoria, many trans adolescents seek assistance from specialised paediatric gender services. Due to substantial increases in the number of referrals to such clinics many trans young people now face waits of >1–2 years to access these services,[7] intensifying their vulnerability to poor mental health.[8]

Trans adolescents are an underserved population that often lack access to targeted and affirming mental health services.[9] Reviews have highlighted the paucity of evidence for effective mental health treatments for this group,[10–12] and the lack of psychological interventions where trans young people have been involved in the development and evaluation of these interventions.[10–12] However, cognitive behavioural therapy (CBT), widely considered the most evidence-based treatment for young people with mental health conditions such as mood, anxiety, and post-traumatic stress disorders,[13–15] is a promising treatment that has the potential to improve health and wellbeing in trans young people experiencing minority stress.

CBT is an umbrella term for psychological treatments which target the relationship between cognitions, behaviours and emotions.[16] These treatments seek to modify the individual's maladaptive cognitive and behavioural patterns by implementing targeted skills and techniques to generate psychological change and improvement of mental health symptoms.[16] When delivered in groups, CBT also facilitates the development of peer connection and the provision of peer support.[17,18] Building on the literature that shows the effectiveness of CBT in addressing mental health conditions in young people, there is growing evidence that demonstrates its potential to alleviate psychological distress in LGBTQIA+ youth through targeting minority stress processes.[19–23] In this context, CBT can be used to assist LGBTQIA+ young people to identify the negative impacts of minority stress and develop skills and techniques to improve their ability to cope with these adverse experiences.[19–23]

A number of studies have provided promising evidence of the effectiveness of CBT interventions that address minority stress in trans adolescents and LGBTQIA+ youth more

broadly. Firstly, an uncontrolled pre-post pilot trial evaluating an 8-session group CBT intervention (AFFIRM) in trans young people aged 16-18 years ($N = 8$) found that AFFIRM resulted in a significant reduction in depression post-intervention and at 3-month follow-up.[19] Other studies of AFFIRM have similarly demonstrated its effectiveness in reducing symptoms of depression among LGBTQIA+ youth generally.[20,21] Additionally, an uncontrolled pre-post pilot feasibility trial evaluating a 7-module online individual CBT intervention (RainbowSPARX) in LGBTQIA+ youth aged 13-19 years ($N = 21$) found that RainbowSPARX resulted in a significant reduction in depression post-intervention and at 3-month follow-up.[23] Finally, a randomised controlled trial (RCT) investigating a 10-session individual CBT intervention (Effective Skills to Empower Effective Men (ESTEEM)) in LGBTQIA+ young men aged 18-35 ($N = 63$) found that ESTEEM resulted in a significant reduction in depressive symptomology post-intervention and at 3-month follow-up.[22] Another RCT evaluating an adaptation of this program, EquIP (Empowering Queer Identities in Psychotherapy), in LGBTQIA+ young women aged 18-35 ($N = 60$) similarly found that EquIP resulted in a significant reduction in depressive symptomology post-intervention and at 3-month follow-up.[24]

While this evidence demonstrates the potential for CBT interventions to improve mental health in LGBTQIA+ youth, there is an ongoing need to develop and evaluate such interventions specifically for trans young people, whose experiences of minority stress and gender-related stigma may differ from those of the broader LGB+ youth community.[25] Moreover, to our knowledge, there have been no published trials that have used participatory research methods to involve trans adolescents in the development and evaluation of CBT interventions targeted to minority stress.

Participatory research is a research paradigm defined by the inclusion of communities in research, so that they can exert power and agency over studies that are intended to benefit or impact them.[26–28] Participation is increasingly being recognised as an important component of all health research, to ensure that studies are conducted *with* rather than *for* or *on* communities.[26] The participation of trans young people is particularly important in this context, as trans young people often experience considerable pathologisation and discrimination in healthcare.[29]

Given the above, this paper describes our protocol for evaluating the feasibility and acceptability of a group CBT intervention that has been developed with an overarching participatory approach and involves trans young people in its design and evaluation. Named TAG TEAM (Trans Adolescent Group ThErapy for Alleviating Minority stress), this intervention has the potential to provide more efficient, timely and targeted psychological support to trans young people, particularly as they wait to access specialist gender-affirming care.

We will initially conduct a feasibility trial with a nested qualitative evaluation, followed by a pilot randomised controlled trial. For the feasibility trial, our primary objective is to determine the feasibility and acceptability of TAG TEAM, including determining whether in person or online delivery is preferable. Our secondary objective is to determine the initial

feasibility and acceptability of the study design and associated procedures, while our exploratory objective is to determine the feasibility, acceptability and effectiveness of different participatory evaluation methods. For the subsequent pilot randomised controlled trial, our primary objective is to determine the feasibility and acceptability of an RCT study design. Taken together, these feasibility and pilot trials will therefore evaluate the feasibility and acceptability of TAG TEAM and inform development of a future, full-scale RCT to formally evaluate its efficacy.

METHODS AND ANALYSIS

TAG TEAM was developed through a qualitative co-design study, which is being reported elsewhere (Chinsen et al., in preparation). Briefly, co-design is a participatory research method underscored by collaboration where consumers participate in the design of new services and products.[30] To co-design TAG TEAM, eight trans young people aged 14-21 years were recruited from the Consumer Advisory Group of the Royal Children's Hospital Gender Service (RCHGS), which includes current and former RCHGS patients. These eight young people participated in a series of co-design workshops facilitated by members of our team with experience working clinically as psychologists and conducting research with trans young people (TC and CP) and a PhD student (AC). In these workshops, participants and facilitators collaborated in activities where they identified targets and strategies for therapeutic intervention, and designed the structure and format of the program. Information garnered from the workshops were then used to develop TAG TEAM.

As a next step, TAG TEAM will be preliminarily evaluated through a feasibility trial with a nested qualitative evaluation followed by a pilot randomised controlled trial. This is described in detail below.

Study design

Feasibility trial

The feasibility trial is an open-label, parallel group feasibility trial (**Figure 1**). Participants will be recruited from the RCHGS waitlist and randomised to TAG TEAM delivered either in-person or online at a 1:1 ratio. Young people and their legal guardian will be invited to express interest in participating in the trial, after which the young person and their legal guardian will provide informed consent and the young person will be screened for eligibility. Young people who provide informed consent and meet all eligibility criteria will be enrolled in the trial. There will be 32 participants (16 per treatment arm, 8 per group). Participant demographics will be recorded at baseline, and participant questionnaire responses (see below) will be measured at baseline and post-treatment.

There will also be a nested qualitative evaluation after the completion of the intervention, where a subset of trial participants will participate in semi-structured interviews and a photovoice study exploring their experience of the program. Up to 15 participants who are enrolled in the feasibility trial will be recruited, and purposive sampling will be undertaken to

include participants with a diverse range of demographic and study characteristics (e.g., gender, age, race, intervention arm). In the semi-structured interviews, participants will be invited to attend a 15-60 minute interview that will explore their experiences of the program and their views and perspectives on its effect on their mental health. The interviews will be audio recorded and transcribed.

Photovoice is a research method with a participatory approach, that involves participants taking photos that respond to study aims or questions and then describing, discussing and displaying the photos.[31] The photovoice study will have three stages. Firstly, participants will be invited to attend an online group meeting where they will be introduced to photovoice methodology and photography. Participants will then be given time to take photos that explore what it means to be a trans young people before and after the program, and their mental health before and after the program. Finally, participants will then be invited to attend an online group meeting where they will describe the photos and engage in facilitated discussion around their meaning, which will be saved.

Both the semi-structured interviews and the photovoice group meetings will be facilitated by members of the research team not involved in the delivery of TAG TEAM.

Pilot trial

Following the conclusion of the feasibility trial, we will conduct a pilot trial (**Figure 2**). The pilot trial is a single-blind, parallel group, randomised controlled pilot trial. Participants will be recruited from the RCHGS waitlist. Young people and their legal guardian will be invited to express interest in participating in the trial, after which the young person and their legal guardian will provide informed consent and the young person will be screened for eligibility. Young people who provide informed consent and meet all eligibility criteria will be enrolled in the trial and randomised to TAG TEAM or a waitlist control at a 1:1 ratio. There will be 64 participants (32 per treatment arm, 8 per group). The trial will be single-blinded and the study investigators will be blinded to treatment allocation while participants will be informed whether they have been allocated to the treatment or control group. Participant demographics will be recorded at baseline, and participant questionnaire responses (see below) will be measured at baseline, post-treatment and 3-month follow-up. Participants in the waitlist control arm will receive TAG TEAM after four and a half months on the waitlist. This comparator was chosen because it was deemed to be unethical to randomise participants who are not yet receiving treatment from the RCHGS to a no-treatment control.[20]

Participants

In both the feasibility and pilot trials, participants will be trans young people on the RCHGS waitlist aged 14-16 years who have current depressive and/or anxious symptomology (as determined by a total score of 8 or above on the Short Mood and Feelings Questionnaire (sMFQ)[32] or a T score of 60 or above on the Spence Children's Anxiety Scale (SCAS) [33]. Participants will be excluded if they have a Multidisciplinary Assessment Clinic appointment scheduled at the RCHGS within six months (to avoid confounding results with

other treatments); have current suicidal symptomology (as determined by a total score of 3 or above on the Columbia-Suicide Severity Rating Scale (C-SSRS)[34] (to manage risk to participants); are actively receiving treatment with any other group psychological intervention at the time of enrolment into the study (to avoid confounding results with other treatments); or are not proficient in English (as the program will be delivered in English). Participants will also be excluded from the pilot trial if they have previously participated in the feasibility trial.

Sample size

As the objective of the feasibility and pilot trials is to evaluate the feasibility and acceptability of the intervention and study design rather than to assess the efficacy of the intervention, there is no statistical justification of sample size needed. We determined the sample size through a consideration of what is necessary to determine feasibility and acceptability,[35] while accounting for attrition based on the ineligibility rate found in similar studies trialling psychological interventions in LGBTQIA+ young people.[22,24] For the feasibility trial, a sample size of 32 participants will allow us to evaluate the feasibility and acceptability of the intervention and study design, with 2 groups of 8 participants in both the in-person and online arms of the study enabling evaluation of acceptability for each treatment arm. For the pilot trial, a sample size of 64 participants will allow us to evaluate the feasibility and acceptability of the randomised controlled trial study design, with 4 groups of 8 participants in both the intervention and waitlist control arms of the study enabling evaluation of acceptability and retention of participants in the intervention and at 3-month follow-up for each treatment arm.

Recruitment

In both the feasibility and pilot trials, participants will be identified via the RCHGS waitlist. The research team will approach the legal guardian of the young person via letter delivered by email or post. The letter will provide information and consent forms for the trial and advise the legal guardian to return an expression of interest if they and their child are interested in participating in the trial. The research team will then initiate contact with the interested legal guardian via phone, where they will provide further information about the trial and answer any questions. If the legal guardian and young person confirm their willingness to participate in the trial and provide informed consent, the research team will undertake eligibility screening with the young person based on the inclusion and exclusion criteria. If the young person meets all eligibility criteria, they will be enrolled into the study. The research team will obtain written informed consent from all young people and their legal guardian.

Randomisation

In the feasibility trial, the randomisation sequence will be prepared by the research team using computer-generated random numbers in consultation with a biostatistician. The participants will be randomised to the in-person or online intervention at a 1:1 ratio, after

which they will be invited to the trial. The allocation will not be concealed from the research team.

In the pilot trial, the randomisation sequence will be prepared by two un-blinded members of the research team using computer-generated random numbers in consultation with a biostatistician. The participants will be randomised to TAG TEAM or a waitlist control at a 1:1 ratio using block randomisation. The allocation will be concealed from the blinded members of the research team, and the two un-blinded members of the research team will not be directly involved in analysis of the trial results.

Intervention

TAG TEAM is a manualised group CBT intervention that focuses on experiences of gender-related minority stress. The intervention was informed by evidence-based CBT principles and minority stress research, and developed with trans young people through an initial co-design study. The intervention consists of six two-hour sessions conducted weekly and facilitated by a trained psychologist and trans peer worker. The intervention sessions each centre on minority stress and CBT principles that aim to address the effects of minority stress. In the feasibility trial, the intervention will be conducted in-person at the RCHGS and online via teleconferencing software, with the latter requiring minor adaptations to the structure of the sessions (e.g., group discussion conducted in break-out rooms). In the pilot trial, the intervention will be conducted in-person at the RCHGS or online via teleconferencing software depending on the outcome of the feasibility trial. Participants will be sent reminders for scheduled intervention sessions.

Fidelity to the treatment protocol will be assessed by facilitators using a checklist at the end of each session to indicate whether each activity in the protocol was not completed (and if so, a reason for non-completion), partially completed (and if so, a reason for partial completion), or completed. The fidelity ratings will be collated by a member of the research team and the facilitators will review their adherence to the protocol in fortnightly supervision sessions with a senior clinician in the research team.

Outcomes

Primary outcomes

In both the feasibility and pilot trials, the primary outcomes are the feasibility and acceptability criteria. The feasibility and acceptability criteria will be used to assess the success of the trials.

The feasibility trial has 10 criteria (**Table 1**); five pertain to the feasibility and acceptability of TAG TEAM itself, and five pertain to the feasibility and acceptability of the study design and associated procedures. The success of the feasibility trial will be assessed based on the number of criteria met, adapted from an assessment framework previously reported[36]: 0–3/10: not feasible/acceptable; 4–7/10: feasible/acceptable with large modifications required; 8-9/10: feasible/acceptable with minor modifications required; 10/10: feasible/acceptable as it

is. The in-person and online intervention arms will be scored separately and compared for feasibility.

Table 1. Primary feasibility and acceptability outcomes for feasibility trial

Objective	Outcome criterion	Conditions for criterion to be met
To determine the feasibility and acceptability of TAG TEAM	Trans young people complete the intervention	More than 80% completion rate for intervention, where completion is defined as attending 5 or more sessions
	The intervention is safe	No serious adverse events or feedback
	The intervention is feasible and acceptable for trans young people	More than 80% of participants evaluate intervention as useful via the Mental Health Statistics Improvement Program Youth Satisfaction Survey (MHSIP)[37]
	The intervention is feasible and acceptable for clinicians	Combined rating of more than 80% from facilitators evaluating intervention as useful via self-developed survey including quantitative and qualitative free-text questions on their views and perceptions of the program
	Preferred method of intervention delivery	Higher recruitment and completion rate for intervention delivery mode Participant and clinician evaluation of intervention delivery mode via MHSIP and self-developed survey
To determine the feasibility and acceptability of the study design and procedures	The eligibility rate (i.e. how many people are eligible to participate in the study over the recruitment period) is feasible and acceptable	Mean of at least 16 eligible participants per month of recruitment
	The participation rate (i.e. how many people who are invited to the study enrol in the study) is feasible and acceptable	Time taken to recruit an initial 35 participants (with a final projected sample size of 32) is less than 2 months (the projected recruitment timeline)

	The loss to follow-up is feasible and acceptable	Less than 20% of participants will be lost to follow-up (where lost to follow-up is defined as missing two consecutive intervention sessions)
	The participant questionnaires are feasible and acceptable	Less than 20% of participants fail to complete all participant questionnaires
	Fidelity to the treatment protocol is feasible and acceptable for clinicians	More than 80% adherence to the treatment protocol

The pilot trial has six criteria which pertain to the feasibility and acceptability of the randomised controlled trial study design (**Table 2**). The success of the pilot trial will be assessed based on the number of criteria met, adapted from an assessment framework previously reported[36]: 0–2/6: not feasible/acceptable; 3–4/6: feasible/acceptable with large modifications required; 5/6: feasible/acceptable with minor modifications required; 6/6: feasible/acceptable as it is.

Table 2. Primary feasibility and acceptability outcomes for pilot trial

Outcome	**Outcome criterion**	**Conditions for criterion to be met**
To determine the feasibility and acceptability of a randomised controlled trial study design	The eligibility rate (i.e. how many people are eligible to participate in the study over the recruitment period) is feasible and acceptable	Mean of 16 eligible participants per month
	The participation rate (i.e. how many people who are invited to the study enrol in the study) is feasible and acceptable	Time taken to recruit an initial 69 participants (with a final projected sample size of 64) is less than 4 months (the projected recruitment timeline)
	The randomisation process is feasible and acceptable for young trans people	Less than 10% non-participation due to randomisation (where non-participation due to randomisation is defined as dropping out of the trial after randomisation and before commencing the intervention)

	The loss to follow-up is feasible and acceptable	Less than 20% of participants will be lost to follow-up (where lost to follow-up is defined as missing two consecutive intervention sessions)
	The participant questionnaires are feasible and acceptable	Less than 20% of participants will fail to complete all participant questionnaires
	Fidelity to the treatment protocol is feasible and acceptable for clinicians	More than 80% adherence to the treatment protocol

Secondary outcomes

In both the feasibility and pilot trials, the secondary outcomes are the participant assessments related to mental health and minority stress. We will assess (1) mood via the Short Mood and Feelings Questionnaire (sMFQ),[32] (2) anxiety via the Spence Children's Anxiety Self-Scale (SCAS),[33] (3) suicidality via the Columbia-Suicide Severity Rating Scale (C-SSRS),[34] (4) quality of life via the Child Health Utility Instrument (CHU 9D),[38] (5), internalised stigma, pride in gender, discrimination and community connectedness via the Gender Minority Stress and Resilience Measure for Adolescents subscales (GMSR-A),[39] (6) gender dysphoria via the Gender Preoccupation and Stability Questionnaire (GPSQ),[40] (7) family support via a questionnaire developed for the Trans20 study,[41] (8) social transition via a questionnaire developed for the Trans20 study,[41] and (9) feasibility, acceptability and usefulness of the intervention via the Mental Health Statistics Improvement Program Youth Satisfaction Survey (MHSIP)[37] and a self-developed survey. The participant questionnaire responses will not be used to measure clinical outcomes but will be used to evaluate the feasibility and acceptability of the questionnaires for participants and the feasibility and acceptability of the intervention. The participant questionnaire responses will be administered online via REDCap[42,43] and participants will be sent reminders.

Analysis

Feasibility and acceptability outcomes

The feasibility and acceptability outcomes will be analysed using the intention-to-treat population. The primary and secondary outcomes will be analysed using descriptive statistics. We will calculate means and standard deviations (or medians and interquartile ranges depending on the distribution of the data), counts and proportions. For the primary outcomes, we will assess and summarise recruitment, retention, baseline, intervention, and follow-up data. For the secondary outcomes, we will assess and summarise questionnaire completion and intervention evaluation data.

Qualitative evaluation

The semi-structured interview and photovoice group meeting data will be analysed using thematic analysis. For the interview and meeting data, we will follow Green and colleagues' analytic framework to explain the themes and patterns in the data.[44] The photovoice photos will be analysed using interpretive engagement, a visual analysis method. For the photos, we will follow Drew and Guillemin's analytic framework to explore the meaning in the data.[45]

Patient and public involvement

Involvement of patients in multiple stages is an important component of the TAG TEAM study. As previously described, current and former patients from the RCHGS Consumer Advisory Group participated in a co-design study where they co-designed the content, structure and format of TAG TEAM with study investigators. Next, participants in the feasibility trial will be invited to participate in semi-structured interviews and a participatory photovoice study where they will take, describe and discuss photos that represent their experience of TAG TEAM.

ETHICS AND DISSEMINATION

The feasibility and pilot trials were approved by the Royal Children's Hospital Human Research Ethics Committee in December 2022 (#91162). Findings from the feasibility and pilot trials will inform the development of an RCT to evaluate the efficacy of TAG TEAM. More broadly, the TAG TEAM study will be used to inform the clinical care of trans young people through the RCHGS and its community partners. Findings will also be disseminated through conference presentations and peer reviewed journal articles.

Trial status

The recruitment of participants is expected to commence in June 2023. The data collection for the feasibility and pilot studies is expected to be completed in April 2024.

DISCUSSION

It is crucial that trans young people have access to effective mental health services targeted to their unique experiences and needs, especially as they wait to access specialist gender-affirming care.[8] This paper outlines the protocol for the preliminary evaluation of TAG TEAM, a co-designed group CBT intervention for trans young people, through a feasibility trial with a nested qualitative evaluation followed by a pilot randomised controlled trial. The outcomes of the trials will be used to inform a full-scale RCT to assess the intervention's efficacy in improving mental health.

The study has a number of key strengths. Firstly, to the best of our knowledge, this is the first study trialling a CBT intervention addressing minority stress developed with and for trans young people specifically. The study thus represents an important contribution to the evidence-base for mental health treatments targeted to this underserved population. Additionally, the use of co-design to develop TAG TEAM means that the content, structure

and format of the program are tailored to the preferences of trans young people, and are more likely to address their experiences and needs.

Furthermore, the study benefits from feasibility and pilot trial design, as the findings from these trials will allow us to improve the intervention and study design to maximise the likelihood of their eventual success. Data from feasibility and pilot trials provide researchers with valuable information on recruitment, retention, and participant assessments, thereby allowing them to refine processes in preparation for full-scale trials.[35] In our case, the feasibility trial will be used to evaluate and modify the group CBT intervention and study design and associated procedures, while the pilot trial will be used to investigate the randomised controlled trial study design and the randomisation and waitlist control procedures. The feasibility and pilot data in this study will therefore be used to improve the intervention and study design before conducting an RCT.

Finally, the study adopts a mixed-methods approach, and the use of qualitative research methods provides greater insight into the experiences, needs and preferences of patients than would have been captured using quantitative data alone. Qualitative research methods allow researchers to understand how patients experience psychological treatments,[46] and moreover captures detailed information about what factors affect their success or failure among different groups.[47] The nested qualitative evaluation data will hence be used to explore the participants' experiences of the group therapy program and their views and perspectives on the program and its effect on their mental health.

The study also has limitations. Firstly, the feasibility trial's small sample size may limit the external validity of the study. Secondly, the recruitment of participants from a clinical population of trans adolescents referred to the RCHGS may limit the generalisability of the study to trans young people who are not seeking specialist gender-affirming care or who are in community settings, and who may thus have different experiences or needs.

In conclusion, the present study aims to preliminarily evaluate a co-designed group CBT intervention for trans young people. The feasibility and pilot trials will be used to inform the development of a full-scale RCT. If TAG TEAM is found to be feasible, acceptable and effective, it may provide more targeted and timely psychological support to trans adolescents, especially in the vulnerable time while they wait to access gender-affirming care.

Acknowledgements: We acknowledge the members of the RCHGS Consumer Advisory Group who participated in the co-design of TAG TEAM. We also acknowledge Associate Professor Michelle Telfer, Dr Zeffie Poulakis and Associate Professor Chris Pepping for their intellectual input into the TAG TEAM study, and Jessica Wilson for research assistance.

Author Contributions: KP, MAT, CP, TC and AC conceptualised the design of the study. AC drafted the manuscript. All authors reviewed and edited the manuscript and approved the final manuscript.

Funding: This work was supported by a Royal Children's Hospital Foundation grant and a Victorian Medical Research Acceleration Fund grant (GA-F4542315-1928).

Competing Interests:

Ken Pang is a member of the World Professional Association for Trans Health. He is also a member of the Australian Professional Association for Trans Health and its research committee, and is also a member of the Editorial Board of the journal Transgender Health.

Michelle Tollit is a member of the Australian Professional Association for Trans Health and is the co-chair of its research committee.

Tim Cronin is a member of the Australian Professional Association for Trans Health.

Carmen Pace is a member of the Australian Professional Association for Trans Health.

Word count: 3,998 words

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Figure 1. Flow diagram of progression of participants through feasibility trial

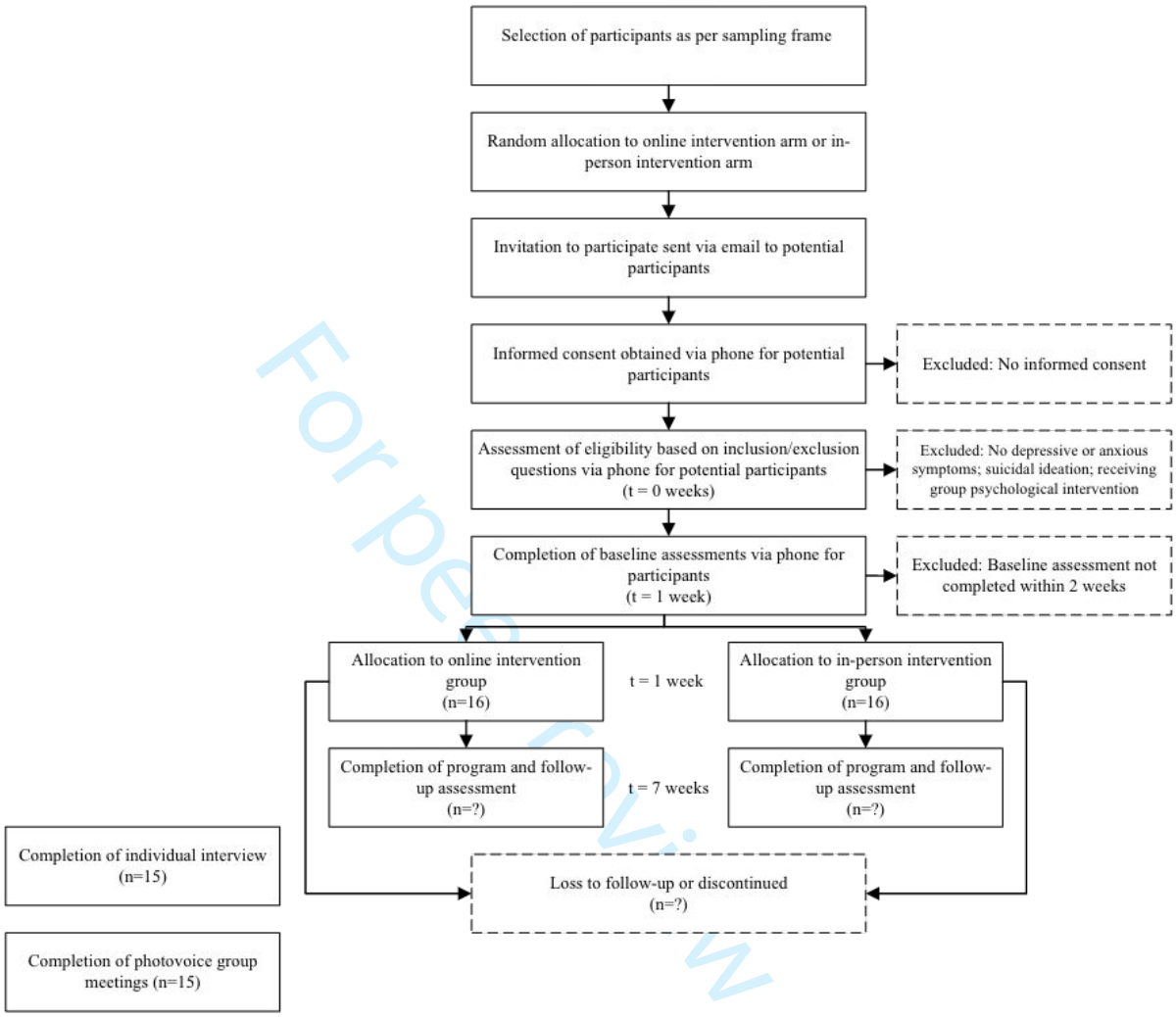
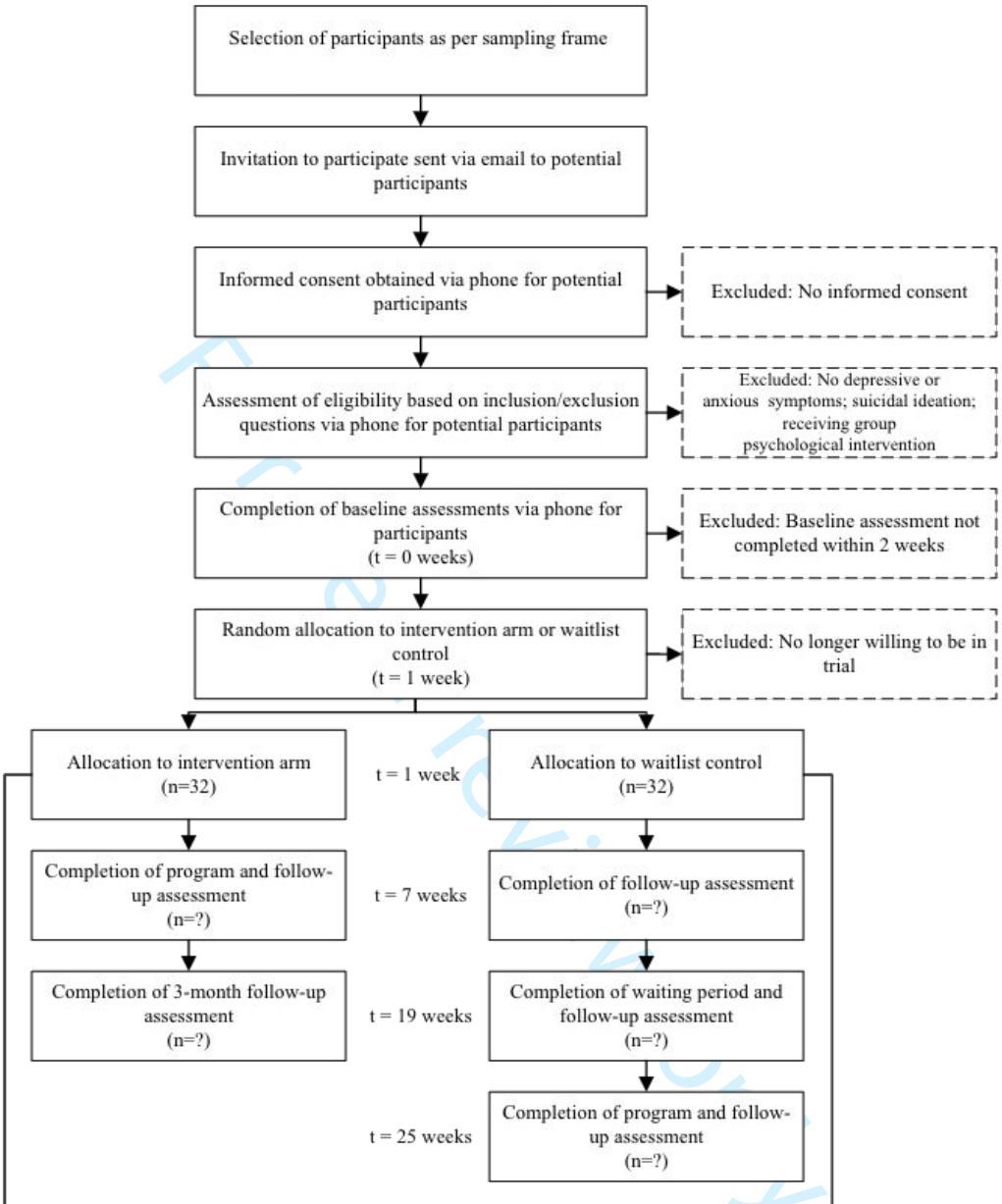


Figure 2. Flow diagram of progression of participants through pilot trial



Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	15
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 14

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7
Objectives	#7	Specific objectives or hypotheses	5-6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6-7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	2
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7-8

		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-12
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6-7, Figure 1, Figure 2
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8-9

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8-9
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-9
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8-9
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8-9
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to	N/A

		protect confidentiality before, during, and after the trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Notes:

- 13: 6-7, Figure 1, Figure 2 The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 09. June 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Evaluation of a co-designed group cognitive behavioural therapy intervention for trans young people (TAG TEAM): protocol for a feasibility trial and a subsequent pilot RCT

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-076511.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Nov-2023
Complete List of Authors:	Chinsen, Alessandra; Murdoch Children's Research Institute, Clinical Sciences; University of Melbourne, Department of Paediatrics Cronin, Tim; Murdoch Children's Research Institute, Clinical Sciences; La Trobe University, Department of Psychology, Counselling and Therapy Pace, Carmen; Murdoch Children's Research Institute, Clinical Sciences; The Royal Children's Hospital Melbourne, Adolescent Medicine Tollit, Michelle; Murdoch Children's Research Institute, Clinical Sciences; The Royal Children's Hospital Melbourne, Adolescent Medicine Pang, Ken; Murdoch Children's Research Institute, Clinical Sciences; The Royal Children's Hospital Melbourne, Adolescent Medicine
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Paediatrics
Keywords:	Adolescent, Transgender Persons, Depression & mood disorders < PSYCHIATRY, Anxiety disorders < PSYCHIATRY, Feasibility Studies

Evaluation of a co-designed group cognitive behavioural therapy intervention for trans young people (TAG TEAM): protocol for a feasibility trial and a subsequent pilot RCT

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ABSTRACT

Introduction: Trans young people are at a higher risk of mental health difficulties such as depression, anxiety and suicidality than their cisgender peers, due in part to their experiences of minority stress. This protocol describes a feasibility trial and subsequent pilot randomised controlled trial (RCT) of a co-designed group cognitive behavioural therapy (CBT) intervention for trans young people, named Trans Adolescent Group ThErapy for Alleviating Minority stress (TAG TEAM).

Methods and analysis: To evaluate TAG TEAM, we will conduct a feasibility trial followed by a pilot RCT with trans young people aged 14-16 years who have been referred to the Royal Children's Hospital Gender Service (RCHGS) in Melbourne, Australia. In the feasibility trial, we aim to enrol 32 participants who will be randomised at a 1:1 ratio to either in-person or online intervention arms. Participants will be assessed at baseline and post-treatment, with a nested qualitative evaluation post-treatment. Primary outcomes are the feasibility and acceptability of the intervention and the study design and associated procedures, including comparison of the in-person and online delivery modes. In the subsequent pilot RCT, we aim to enrol 64 participants who will be randomised at a 1:1 ratio to an intervention or waitlist control arm, with delivery mode determined by the feasibility trial. Participants will complete assessments at baseline, post-treatment and 3-month follow-up. Primary outcomes are the feasibility and acceptability of the randomised controlled trial study design. In both the feasibility trial and pilot RCT, participants will complete assessments related to mood, anxiety, suicidality, quality of life, minority stress, family support and social transition. Quantitative data will be analysed using descriptive statistics. Qualitative data will be analysed using thematic and interpretive analysis.

Ethics and dissemination: The Royal Children's Hospital Human Research Ethics Committee has approved this study (#91162). Informed consent will be obtained in writing from all participants and a legal guardian. Findings will inform the development of a full-scale RCT to evaluate the efficacy of TAG TEAM and will be disseminated through conferences and peer reviewed journals.

Trial registration numbers: Feasibility trial: ACTRN12623000302651. Pilot RCT: ACTRN12623000318684.

ARTICLE SUMMARY

Strengths and limitations of this study

- TAG TEAM is based on the needs and preferences of trans young people and centres on themes related to minority stress and cognitive behavioural therapy (CBT) principles.
- The feasibility and pilot randomised controlled trial (RCT) study design will allow us to assess and improve TAG TEAM before proceeding to a full-scale RCT.
- The feasibility trial's nested qualitative evaluation and use of participatory evaluation methods will allow us to understand the experiences, needs and preferences of trans young people.
- The feasibility trial's small sample size may limit external validity.
- The feasibility trial and pilot RCT will recruit from a clinical population of trans young people referred to a paediatric gender service, and this may limit generalisability to other populations.

INTRODUCTION

Transgender and gender diverse (hereafter trans) are terms used to describe people whose gender is different from the sex assigned to them at birth. Trans young people are at high risk of mental health conditions such as anxiety, depression and suicidality.[1–3] This poor mental health is in part associated with the abuse, rejection and discrimination that trans young people frequently experience in broader society.[1–3] These experiences are referred to as minority stressors,[4] and are theorised to contribute to psychological distress in trans people through engendering self-blame, self-hate and low self-esteem.[5] For example, a study of 859 trans young people found high rates of adverse experiences such as peer rejection (89.0%), bullying (74.0%) and discrimination (68.9%), and noted that these experiences were associated with depression, suicidality and anxiety.[6]

In addition, many trans young people's mental health is adversely affected by gender dysphoria, which is distress associated with an incongruence between gender and sex assigned at birth. To help address this dysphoria, many trans adolescents seek assistance from specialised paediatric gender services. Due to substantial increases in the number of referrals to such clinics many trans young people now face waits of >1–2 years to access these services,[7] intensifying their vulnerability to poor mental health.[8]

Trans adolescents are an underserved population that often lack access to targeted and affirming mental health services.[9] Reviews have highlighted the paucity of evidence for effective mental health treatments for this group,[10–12] and the lack of psychological interventions where trans young people have been involved in the development and evaluation of these interventions.[10–12] However, cognitive behavioural therapy (CBT), widely considered the most evidence-based treatment for young people with mental health conditions such as mood, anxiety and post-traumatic stress disorders,[13–15] is a promising treatment that has the potential to improve health and wellbeing in trans young people experiencing minority stress.

CBT is an umbrella term for psychological treatments which target the relationship between cognitions, behaviours and emotions.[16] These treatments seek to modify the individual's maladaptive cognitive and behavioural patterns by implementing targeted skills and techniques to generate psychological change and improvement of mental health symptoms.[16] When delivered in groups, CBT also facilitates the development of peer connection and the provision of peer support.[17,18] Building on the literature that shows the effectiveness of CBT in addressing mental health conditions in young people, there is growing evidence that demonstrates its potential to alleviate psychological distress in lesbian, gay, bisexual, trans, queer, intersex and asexual (LGBTQIA+) youth through targeting minority stress processes.[19–23] Recent studies have also shown an association between peer connection and support and improved psychological wellbeing in LGBTQIA+ people more broadly,[24,25] which is theorised to be a result of peers sharing and validating minority experiences and identities.[4] In this context, CBT can be used to assist LGBTQIA+ young people to identify the negative impacts of minority stress and develop skills and

techniques to improve their ability to cope with these adverse experiences,[19–23] and group CBT could provide further benefits through the facilitation of peer relationships.[24,25]

A number of studies have provided promising evidence of the effectiveness of CBT interventions that address minority stress in trans adolescents and LGBTQIA+ youth more broadly. Firstly, based on a model of transgender affirmative CBT (TA-CBT),[26] an uncontrolled pre-post pilot trial evaluating an 8-session group CBT intervention (AFFIRM) in trans young people aged 16-18 years ($N = 8$) found that AFFIRM resulted in a significant reduction in depression post-intervention and at 3-month follow-up.[19] Other studies of AFFIRM have similarly demonstrated its effectiveness in reducing symptoms of depression among LGBTQIA+ youth generally.[20,21] Additionally, an uncontrolled pre-post pilot feasibility trial evaluating a 7-module online individual CBT intervention (RainbowSPARX) in LGBTQIA+ youth aged 13-19 years ($N = 21$) found that RainbowSPARX resulted in a significant reduction in depression post-intervention and at 3-month follow-up.[23] Finally, a randomised controlled trial (RCT) investigating a 10-session individual CBT intervention (Effective Skills to Empower Effective Men (ESTEEM)) in LGBTQIA+ young men aged 18-35 ($N = 63$) found that ESTEEM resulted in a significant reduction in depressive symptomology post-intervention and at 3-month follow-up.[22] Another RCT evaluating an adaptation of this program, EquIP (Empowering Queer Identities in Psychotherapy), in LGBTQIA+ young women aged 18-35 ($N = 60$) similarly found that EquIP resulted in a significant reduction in depressive symptomology post-intervention and at 3-month follow-up.[27]

While this evidence demonstrates the potential for CBT interventions to improve mental health in LGBTQIA+ youth, there is an ongoing need to develop and evaluate such interventions specifically for trans young people, whose experiences of minority stress and gender-related stigma may differ from those of the broader LGB+ youth community.[28] Moreover, there is a need to involve trans adolescents in the development and evaluation of CBT interventions targeted to minority stress, such as through the use of participatory research methods.

Participatory research is a research paradigm defined by the inclusion of communities in research, so that they can exert power and agency over studies that are intended to benefit or impact them.[29–31] Participation is increasingly being recognised as an important component of all health research, to ensure that studies are conducted *with* rather than *for* or *on* communities.[29] The participation of trans young people is particularly important in this context, as trans young people often experience considerable pathologisation and discrimination in healthcare.[32]

Given the above, this paper describes our protocol for evaluating the feasibility and acceptability of a group CBT intervention that has been developed with an overarching participatory approach and involves trans young people in its design and evaluation. Named TAG TEAM (Trans Adolescent Group ThErapy for Alleviating Minority stress), this intervention has the potential to provide more efficient, timely and targeted psychological

support to trans young people, particularly as they wait to access specialist gender-affirming care.

We will initially conduct a feasibility trial with a nested qualitative evaluation, followed by a pilot RCT. For the feasibility trial, our primary objective is to determine the feasibility and acceptability of the TAG TEAM program, including determining whether in-person or online delivery is preferable. Our secondary objective is to determine the initial feasibility and acceptability of the study design (e.g., recruitment methods). Our exploratory objective is to determine the feasibility, acceptability and effectiveness of using participatory research methods to evaluate mental health interventions. For the subsequent pilot RCT, our primary objective is to determine the feasibility and acceptability of an RCT study design. Taken together, this feasibility trial and pilot RCT will therefore evaluate the feasibility and acceptability of TAG TEAM and inform the development of a future, full-scale RCT to formally evaluate its efficacy.

METHODS AND ANALYSIS

TAG TEAM was previously developed through a qualitative co-design study, which is being reported elsewhere (Chinsen et al., in preparation). Briefly, co-design is a participatory research method underscored by collaboration where consumers participate in the design of new services and products.[33] To co-design TAG TEAM, eight trans young people aged 14-21 years were recruited from the Consumer Advisory Group of the Royal Children's Hospital Gender Service (RCHGS), which includes current and former RCHGS patients. These eight young people participated in a series of co-design workshops facilitated by members of our team with experience working clinically as psychologists and conducting research with trans young people (TC and CP) and a PhD student (AC). In these workshops, participants and facilitators collaborated in activities where they identified targets and strategies for therapeutic intervention and designed the structure and format of the program. Information garnered from the workshops were then used to develop TAG TEAM.

As a next step, TAG TEAM will be preliminarily evaluated through a feasibility trial with a nested qualitative evaluation followed by a pilot RCT. This is described in detail below according to the Standard Protocol Items: Recommendations for Interventional Trials checklist.[34]

Study design

Feasibility trial

The feasibility trial is an open-label, parallel group feasibility trial (**Figure 1**). Participants will be recruited from the RCHGS waitlist and randomised to TAG TEAM delivered either in-person or online at a 1:1 ratio. Young people and their legal guardian will be invited to express interest in participating in the trial, after which the young person and their legal guardian will provide informed consent and the young person will be screened for eligibility. Young people who provide informed consent and meet all eligibility criteria will be enrolled

in the trial. There will be 32 participants (16 per treatment arm, 8 per group). Participant demographics will be recorded at baseline, and participant questionnaire responses (see below) will be measured at baseline and post-treatment.

There will also be a nested qualitative evaluation after the completion of the intervention, where a subset of trial participants will participate in semi-structured interviews and a photovoice study exploring their experience of the program. Up to 15 participants who are enrolled in the feasibility trial will be recruited, to ensure that a breadth of participant experiences and perspectives are captured while also allowing us to analyse data in depth. We will undertake purposive sampling to include participants with a diverse range of demographic and study characteristics (e.g., gender, age, race, intervention arm). In the semi-structured interviews, participants will be invited to attend a 15-60 minute interview that will explore their experiences of the program and their views and perspectives on its effect on their mental health. The interviews will be audio recorded and transcribed.

Photovoice is a research method with a participatory approach, which involves participants taking photos that respond to study aims or questions and then describing, discussing and displaying the photos.[35] The photovoice study will have three stages. Firstly, participants will be invited to attend an online group meeting where they will be introduced to photovoice methodology and photography. Participants will then be given time to take photos that explore what it means to be a trans young people before and after the program, and their mental health before and after the program. Finally, participants will then be invited to attend an online group meeting where they will describe the photos and engage in facilitated discussion around their meaning, which will be saved.

Both the semi-structured interviews and the photovoice group meetings will be facilitated by members of the research team not involved in the delivery of TAG TEAM.

Pilot RCT

Following the conclusion of the feasibility trial, we will conduct a pilot RCT (**Figure 2**). The pilot RCT is a single-blind, parallel group RCT. Participants will be recruited from the RCHGS waitlist. Young people and their legal guardian will be invited to express interest in participating in the trial, after which the young person and their legal guardian will provide informed consent and the young person will be screened for eligibility. Young people who provide informed consent and meet all eligibility criteria will be enrolled in the trial and randomised to TAG TEAM or a waitlist control at a 1:1 ratio. There will be 64 participants (32 per treatment arm, 8 per group). The trial will be single-blinded and the study investigators will be blinded to treatment allocation while participants will be informed whether they have been allocated to the treatment or control group. Participant demographics will be recorded at baseline, and participant questionnaire responses (see below) will be measured at baseline, post-treatment and 3-month follow-up. Participants in the waitlist control arm will receive TAG TEAM after four and a half months on the waitlist (which corresponds to when participants in the intervention arm have completed the 6-week intervention and 3-month follow-up assessment). This comparator was chosen because it was

deemed to be unethical to randomise participants who are not yet receiving treatment from the RCHGS to a no-treatment control.[20]

Participants

In both the feasibility trial and pilot RCT, participants will be trans young people on the RCHGS waitlist aged 14-16 years who have current depressive and/or anxious symptomology (as determined by a total score of 8 or above on the Short Mood and Feelings Questionnaire (sMFQ)[36] or a T score of 60 or above on the Spence Children's Anxiety Scale (SCAS) [37]. Participants will be excluded if they have a Multidisciplinary Assessment Clinic appointment scheduled at the RCHGS within six months (to avoid confounding results with other treatments); have current suicidal symptomology (as determined by a total score of 3 or above on the Columbia-Suicide Severity Rating Scale (C-SSRS)[38] (to manage risk to participants); are actively receiving treatment with any other group psychological intervention at the time of enrolment into the study (to avoid confounding results with other treatments); or are not proficient in English (as the program will be delivered in English). Participants will also be excluded from the pilot RCT if they have previously participated in the feasibility trial.

Sample size

As the objective of the feasibility trial and pilot RCT is to evaluate the feasibility and acceptability of the TAG TEAM program and study design rather than to assess the efficacy of the intervention, sample size was chosen on the basis of feasibility and practicality,[39] and did not require a statistical power calculation.[40] We determined the sample size through a consideration of the number of participants necessary to evaluate feasibility and acceptability of the intervention and study design across a breadth of trans young people, while accounting for attrition based on the ineligibility rate found in similar studies trialling psychological interventions in LGBTQIA+ young people.[22,27] We also considered practical needs such as the estimated time needed for recruitment and the intervention.

For the feasibility trial, we will aim to recruit 35 participants to achieve a sample size of 32 enrolled participants accounting for ineligibility. This will allow us to evaluate the feasibility and acceptability of the intervention and study design, with 2 groups of 8 participants in both the in-person and online arms of the study enabling evaluation of acceptability for each treatment arm.

For the pilot RCT, we will aim to recruit 69 participants to achieve a sample size of 64 enrolled participants accounting for ineligibility. This will allow us to evaluate the feasibility and acceptability of the RCT study design, with 4 groups of 8 participants in both the intervention and waitlist control arms of the study enabling evaluation of acceptability and retention of participants in the intervention and at 3-month follow-up for each treatment arm.

Recruitment

In both the feasibility trial and pilot RCT, participants will be identified via the RCHGS waitlist. The research team will approach the legal guardian of the young person via letter delivered by email or post. The letter will provide information and consent forms for the trial and advise the legal guardian to return an expression of interest if they and their child are interested in participating in the trial (Supplemental Material, **Appendix A** and **Appendix B**). The research team will then initiate contact with the interested legal guardian via phone, where they will provide further information about the trial and answer any questions. If the legal guardian and young person confirm their willingness to participate in the trial and provide informed consent, the research team will undertake eligibility screening with the young person based on the inclusion and exclusion criteria. If the young person meets all eligibility criteria, they will be enrolled into the study. The research team will obtain written informed consent from all young people and their legal guardian.

Randomisation

In the feasibility trial, the randomisation sequence will be prepared by the research team using computer-generated random numbers in consultation with a biostatistician. The participants will be randomised to the in-person or online intervention at a 1:1 ratio, after which they will be invited to the trial. The allocation will not be concealed from the research team.

In the pilot RCT, the randomisation sequence will be prepared by two un-blinded members of the research team using computer-generated random numbers in consultation with a biostatistician. The participants will be randomised to TAG TEAM or a waitlist control at a 1:1 ratio using block randomisation, and they will be informed of their treatment allocation by the un-blinded members of the research team. The allocation will be concealed from the blinded members of the research team, and the two un-blinded members of the research team will not be directly involved in collection of data or analysis of the trial results.

Intervention

TAG TEAM is a manualised group CBT intervention that focuses on experiences of gender-related minority stress. The intervention was informed by evidence-based CBT principles and minority stress research, and developed with trans young people through an initial co-design study. The intervention consists of six two-hour sessions conducted weekly and facilitated by a trained psychologist and trans peer worker. The intervention sessions each centre on minority stress and CBT principles that aim to address the effects of minority stress. In the feasibility trial, the intervention will be conducted in-person at the RCHGS and online via teleconferencing software, with the latter requiring minor adaptations to the structure of the sessions (e.g., group discussion conducted in break-out rooms). In the pilot RCT, the intervention will be conducted in-person at the RCHGS or online via teleconferencing software depending on the outcome of the feasibility trial. Participants will be sent reminders for scheduled intervention sessions.

At the conclusion of the intervention, facilitators will provide participants with information about other services they can access for support. Participants may discontinue the trial intervention at the request of themselves or their legal guardian, or at request of the investigators in the case of significant intervention non-compliance or a serious adverse event.

Fidelity to the treatment protocol will be assessed by facilitators using a checklist at the end of each session to indicate whether each activity in the protocol was not completed (and if so, a reason for non-completion), partially completed (and if so, a reason for partial completion), or completed. The fidelity ratings will be collated by a member of the research team and the facilitators will monitor and support their adherence to the protocol in fortnightly supervision sessions with a senior clinician in the research team.

Outcomes

Primary outcomes

In both the feasibility trial and pilot RCT, the primary outcomes are the feasibility and acceptability criteria. The feasibility and acceptability criteria will be used to assess the success of the trials.

The feasibility trial has 10 criteria (**Table 1**); five pertain to the feasibility and acceptability of TAG TEAM itself, and five pertain to the feasibility and acceptability of the study design and associated procedures. The success of the feasibility trial will be assessed based on the number of criteria met, adapted from an assessment framework previously reported[41]: 0–3/10: not feasible/acceptable; 4–7/10: feasible/acceptable with large modifications required; 8-9/10: feasible/acceptable with minor modifications required; 10/10: feasible/acceptable as it is. The in-person and online intervention arms will be scored separately and compared for feasibility.

Table 1. Primary feasibility and acceptability outcomes for feasibility trial

Objective	Outcome criterion	Conditions for criterion to be met
To determine the feasibility and acceptability of TAG TEAM	Trans young people complete the intervention	More than 80% completion rate for intervention, where completion is defined as attending 5 or more sessions
	The intervention is safe	No serious adverse events or feedback related to the intervention
	The intervention is feasible and acceptable for trans young people	More than 80% of participants evaluate intervention as useful via investigator-developed survey including quantitative and

		qualitative free-text questions on their views and perceptions of the program (Supplemental Material, **Appendix C**)
	The intervention is feasible and acceptable for clinicians	Combined rating of more than 80% from facilitators evaluating intervention as useful via investigator-developed survey including quantitative and qualitative free-text questions on their views and perceptions of the program (Supplemental Material, **Appendix D**)
	Preferred method of intervention delivery	Higher recruitment and completion rate for intervention delivery mode Participant and clinician evaluation of intervention delivery mode via investigator-developed surveys
To determine the feasibility and acceptability of the study design and procedures	The eligibility rate (i.e. how many people are eligible to participate in the study over the recruitment period) is feasible and acceptable	Mean of at least 16 eligible participants per month of recruitment
	The participation rate (i.e. how many people who are invited to the study enrol in the study) is feasible and acceptable	Time taken to recruit an initial 35 participants (with a final projected sample size of 32) is less than 2 months (the projected recruitment timeline)
	The loss to follow-up is feasible and acceptable	Less than 20% of participants will be lost to follow-up (where lost to follow-up is defined as missing two consecutive intervention sessions)
	The participant questionnaires are feasible and acceptable	Less than 20% of participants fail to complete all participant questionnaires
	Fidelity to the treatment protocol is feasible and acceptable for clinicians	More than 80% adherence to the treatment protocol

The pilot RCT has six criteria which pertain to the feasibility and acceptability of the RCT study design (**Table 2**). The success of the pilot RCT will be assessed based on the number of criteria met, adapted from an assessment framework previously reported[41]: 0–2/6: not feasible/acceptable; 3–4/6: feasible/acceptable with large modifications required; 5/6: feasible/acceptable with minor modifications required; 6/6: feasible/acceptable as it is.

Table 2. Primary feasibility and acceptability outcomes for pilot trial RCT

Outcome	**Outcome criterion**	**Conditions for criterion to be met**
To determine the feasibility and acceptability of a randomised controlled trial study design	The eligibility rate (i.e. how many people are eligible to participate in the study over the recruitment period) is feasible and acceptable	Mean of 16 eligible participants per month
	The participation rate (i.e. how many people who are invited to the study enrol in the study) is feasible and acceptable	Time taken to recruit an initial 69 participants (with a final projected sample size of 64) is less than 4 months (the projected recruitment timeline)
	The randomisation process is feasible and acceptable for young trans people	Less than 10% non-participation due to randomisation (where non-participation due to randomisation is defined as dropping out of the trial after randomisation and before commencing the intervention)
	The loss to follow-up is feasible and acceptable	Less than 20% of participants will be lost to follow-up (where lost to follow-up is defined as missing two consecutive intervention sessions)
	The participant questionnaires are feasible and acceptable	Less than 20% of participants will fail to complete all participant questionnaires
	Fidelity to the treatment protocol is feasible and acceptable for clinicians	More than 80% adherence to the treatment protocol

Secondary outcomes

In both the feasibility trial and pilot RCT, the secondary outcomes are the participant assessments related to mental health and minority stress. The participant assessments will not be used to assess changes in clinical outcomes, but will instead be used to evaluate the feasibility and acceptability of administering the questionnaires to participants and the feasibility and acceptability of the intervention. We will assess (1) mood via the Short Mood and Feelings Questionnaire (sMFQ),[36] (2) anxiety via the Spence Children's Anxiety Self-Scale (SCAS),[37] (3) suicidality via the Columbia-Suicide Severity Rating Scale (C-SSRS),[38] (4) quality of life via the Child Health Utility Instrument (CHU 9D),[42] (5), internalised stigma, pride in gender, discrimination and community connectedness via the Gender Minority Stress and Resilience Measure for Adolescents subscales (GMSR-A),[43] (6) gender dysphoria via the Gender Preoccupation and Stability Questionnaire (GPSQ),[44] (7) family support via a questionnaire developed for the Trans20 study,[45] (8) social transition via a questionnaire developed for the Trans20 study,[45] and (9) feasibility, acceptability and usefulness of the intervention via investigator-developed surveys for participants and facilitators. The participant questionnaire responses will be administered online via REDCap[46,47] and participants will be sent reminders.

Safety and monitoring

The study investigator will be responsible for collecting, assessing, reporting and managing adverse events. The study investigator will report any serious adverse events or adverse events that present an immediate risk to a participant's health or safety to the trial sponsor and institutional ethics committee. Given that the feasibility trial and pilot RCT are preliminary trials being conducted over short periods of time, a formal data monitoring committee and auditing committee were not deemed necessary. The research team will meet regularly to review data collection and trial procedures.

Analysis

Feasibility and acceptability outcomes

The feasibility and acceptability outcomes will be analysed using the intention-to-treat population. The primary and secondary outcomes will be analysed using descriptive statistics. We will calculate means and standard deviations (or medians and interquartile ranges depending on the distribution of the data), counts and proportions. For the primary outcomes, we will assess and summarise recruitment, retention, baseline, intervention, and follow-up data. For the secondary outcomes, we will assess and summarise questionnaire completion and intervention evaluation data.

Qualitative evaluation

The semi-structured interview and photovoice group meeting data will be analysed using thematic analysis. For the interview and meeting data, we will follow Green and colleagues' analytic framework to explain the themes and patterns in the data.[48] The photovoice photos

will be analysed using interpretive engagement, a visual analysis method. For the photos, we will follow Drew and Guillemin's analytic framework to explore the meaning in the data.[49]

Patient and public involvement

Involvement of patients in multiple stages is an important component of the TAG TEAM study. As previously described, current and former patients from the RCHGS Consumer Advisory Group participated in a co-design study where they co-designed the content, structure and format of TAG TEAM with study investigators. Next, participants in the feasibility trial will be invited to participate in semi-structured interviews and a participatory photovoice study where they will take, describe and discuss photos that represent their experience of TAG TEAM.

ETHICS AND DISSEMINATION

Ethics

The feasibility trial and pilot RCT were approved by the Royal Children's Hospital Human Research Ethics Committee in December 2022 (#91162). Important protocol modifications will be communicated to the institutional ethics committee and will be updated in the ANZCTR. Informed consent will be obtained in writing from all participants and a legal guardian.

Confidentiality

Participant identifiers will be stored separate from any collected data in secure databases, and access to these identifiers will be restricted to the research team and authorised persons. To further preserve confidentiality, the amount of identifying information collected for each participant has been minimised.

Dissemination

Findings from the feasibility trial and pilot RCT will inform the development of a full-scale RCT to evaluate the efficacy of TAG TEAM. More broadly, the TAG TEAM study will be used to inform the clinical care of trans young people through the RCHGS and its community partners. Findings will also be disseminated through conference presentations and peer reviewed journal articles. The feasibility trial and pilot RCT data will be available on request.

Trial status

The recruitment of participants is expected to commence in June 2023. The data collection for the feasibility and pilot studies is expected to be completed in April 2024.

DISCUSSION

It is crucial that trans young people have access to effective mental health services targeted to their unique experiences and needs, especially as they wait to access specialist gender-

affirming care.[8] This paper outlines the protocol for the preliminary evaluation of TAG TEAM, a co-designed group CBT intervention for trans young people, through a feasibility trial with a nested qualitative evaluation followed by a pilot RCT. The outcomes of the trials will be used to inform a full-scale RCT to assess the intervention's efficacy in improving mental health.

The study has a number of key strengths. Firstly, the study trials a CBT intervention addressing minority stress developed with and for trans young people specifically. The study thus represents an important contribution to the evidence-base for mental health treatments targeted to this underserved population. Additionally, the use of co-design to develop TAG TEAM means that the content, structure and format of the program are tailored to the preferences of trans young people and are more likely to address their experiences and needs, which has been found to be an important consideration when delivering CBT interventions to this group.[50]

Furthermore, the study benefits from the feasibility trial and pilot RCT design, as the findings from these trials will allow us to improve the intervention and study design to maximise the likelihood of their eventual success. Data from feasibility trials and pilot RCTs provide researchers with valuable information on recruitment, retention and participant assessments, thereby allowing them to refine processes in preparation for full-scale trials.[40] In our case, the feasibility trial will be used to evaluate and modify the group CBT intervention and study design and associated procedures, while the pilot RCT will be used to investigate the RCT study design and the randomisation and waitlist control procedures. The feasibility and pilot data in this study will therefore be used to improve the intervention and study design before conducting a full-scale RCT.

Finally, the study adopts a mixed-methods approach, and the use of qualitative research methods provides greater insight into the experiences, needs and preferences of patients than would have been captured using quantitative data alone. Qualitative research methods allow researchers to understand how patients experience psychological treatments,[51] and moreover captures detailed information about what factors affect their success or failure among different groups.[52] The nested qualitative evaluation data will hence be used to explore the participants' experiences of the group therapy program and their views and perspectives on the program and its effect on their mental health.

The study also has limitations. Firstly, the feasibility trial's small sample size may limit the external validity of the study. Secondly, the recruitment of participants from a clinical population of trans adolescents referred to the RCHGS may limit the generalisability of the study to trans young people who are not seeking specialist gender-affirming care or who are in community settings, and who may thus have different experiences or needs.

In conclusion, the present study aims to preliminarily evaluate a co-designed group CBT intervention for trans young people. The feasibility trial and pilot RCT will be used to inform the development of a full-scale RCT. If TAG TEAM is found to be feasible, acceptable and

effective, it may provide more targeted and timely psychological support to trans adolescents, especially in the vulnerable time while they wait to access gender-affirming care.

Acknowledgements: We acknowledge Kayden Crombie, Alice Jacka, Jessica Sutherland and the other members of the RCHGS Consumer Advisory Group who participated in the co-design of TAG TEAM. We also acknowledge Associate Professor Michelle Telfer, Dr Zeffie Poulakis and Associate Professor Chris Pepping for their intellectual input into the TAG TEAM study, and Jessica Wilson for research assistance.

Contributors: KP, MAT, CP, TC and AC conceptualised the design of the study. AC drafted the manuscript. All authors reviewed and edited the manuscript and approved the final manuscript.

Funding: This work was supported by a Royal Children's Hospital Foundation grant and a Victorian Medical Research Acceleration Fund grant (GA-F4542315-1928). They did not have a role in the conceptualisation or conduct of the study.

Competing interests: Ken Pang is a member of the World Professional Association for Trans Health. He is also a member of the Australian Professional Association for Trans Health and its research committee and a member of the Editorial Board of the journal *Transgender Health*. Michelle Tollit is a member of the Australian Professional Association for Trans Health and is the co-chair of its research committee. Tim Cronin is a member of the Australian Professional Association for Trans Health. Carmen Pace is a member of the Australian Professional Association for Trans Health. Alessandra Chinsen declares no competing interests.

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Figure titles:

Figure 1. Flow diagram of progression of participants through feasibility trial

Figure 2. Flow diagram of progression of participants through pilot RCT

Figure 1. Flow diagram of progression of participants through feasibility trial

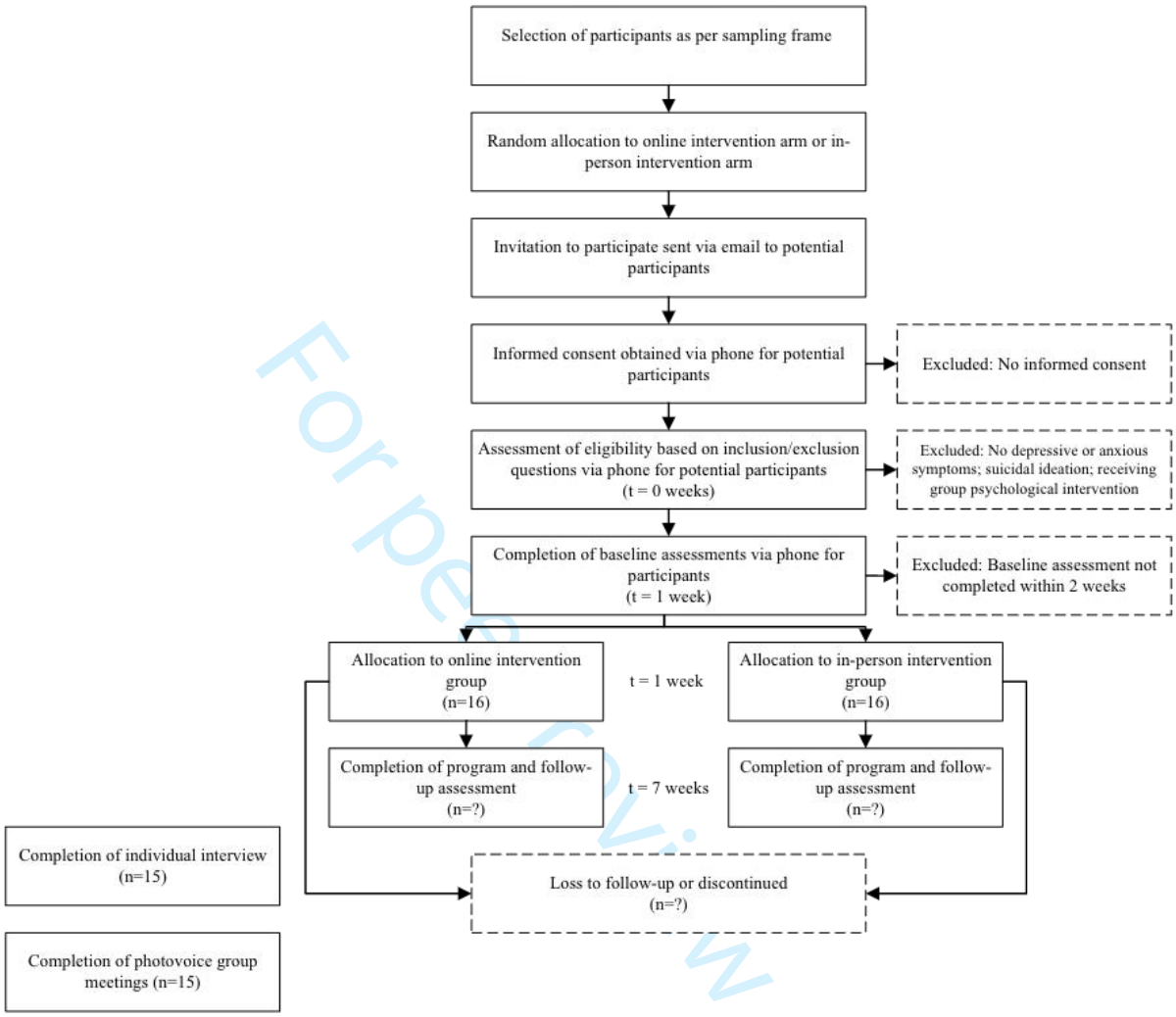
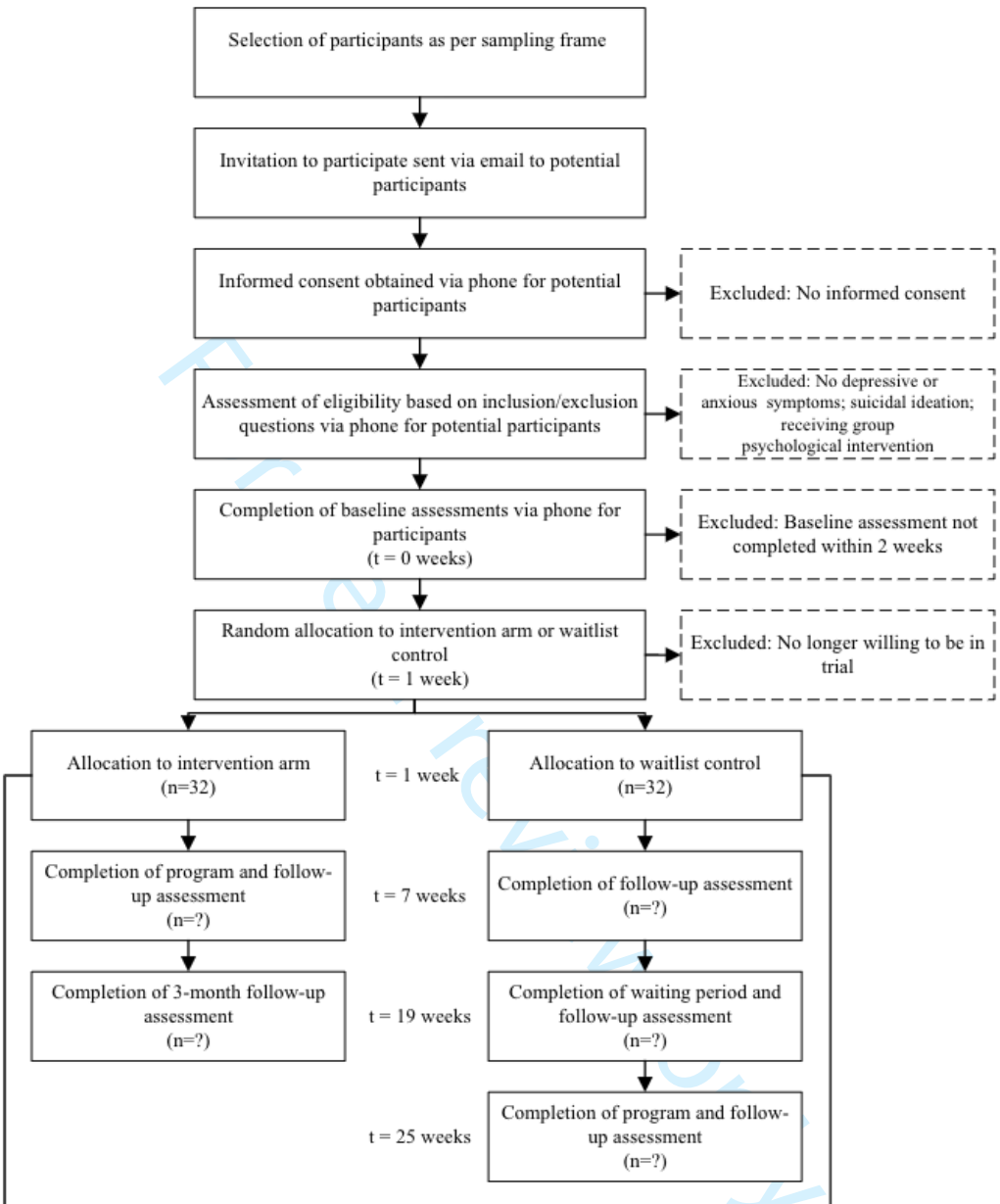


Figure 2. Flow diagram of progression of participants through pilot RCT



Appendix A. Example of feasibility trial participant consent form

Consent Form

Study Number:	91162
Short Name of Project:	Evaluation of Trans Adolescent Group ThErapy for Alleviating Minority stress (TAG TEAM)

Version Number:	5	**Version Date:**	12/07/2023

- I have read this information statement and I understand its contents.
- I understand what I have to do in this project.
- I understand the risks I could face because of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Participant Name	Participant Signature	Date
Name of Witness to Participant's Signature	Witness Signature	Date

Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name	Research Team Member Signature	Date

Note: All parties signing the Consent Form must date their own signature.

Appendix B. Example of pilot RCT participant consent form

Consent Form

Study Number:	91162
Short Name of Project:	Evaluation of Trans Adolescent Group ThErapy for Alleviating Minority stress (TAG TEAM)

Version Number:	4	**Version Date:**	01/12/2022

- I have read this information statement and I understand its contents.
- I understand what I have to do in this project.
- I understand the risks I could face because of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Participant Name	Participant Signature	Date
Name of Witness to Participant's Signature	Witness Signature	Date

Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name	Research Team Member Signature	Date

Note: All parties signing the Consent Form must date their own signature.

Appendix C. Investigator-developed evaluation survey for participants

TAG TEAM participant evaluation survey

The following questions are about your overall experience of the TAG TEAM program. Please indicate your responses on the scale below.

		1 – Strongly disagree	2 – Somewhat disagree	3 – Neutral	4 – Somewhat agree	5 – Strongly agree
1	**Overall, I thought the TAG TEAM program was appropriate for trans young people**					
2	**Overall, I thought the TAG TEAM program was useful**					
3	**Overall, I was satisfied with the TAG TEAM program**					
4	**I would recommend TAG TEAM to trans young people**					

The following questions are about specific parts of the TAG TEAM program. Please indicate your responses on the scale below.

5	**Overall, I thought the following TAG TEAM activities were useful**	1 – Strongly disagree	2 – Somewhat disagree	3 – Neutral	4 – Somewhat agree	5 – Strongly agree
	Information about Cognitive Behavioural therapy					
	Information about minority stress (e.g., pride, internalised stigma, discrimination, community connectedness)					
	Discussion about session themes in groups					
	Between-session activities					
	Watching videos of trans adults					

	Connecting with other trans young people					
	Activities completed by myself					
	Activities completed with other people in the group					
	The TAG TEAM workbook used for completing in-session and between-session activities					
	Other [Please specify]					

6	**What suggestions, if any, do you have for improving the TAG TEAM program?**

Appendix D. Investigator-developed evaluation survey for facilitators

TAG TEAM facilitator evaluation survey

Training

The following questions are about the TAG TEAM facilitator training. Please indicate your responses on the scale below.

		1 – Strongly disagree	2 – Somewhat disagree	3 – Neutral	4 – Somewhat agree	5 – Strongly agree
1	**The content of the facilitator training was appropriate for delivering the TAG TEAM program**					
2	**The length of the facilitator training was appropriate for delivering the TAG TEAM program**					

Session content

The following questions are about **Session 1 (Introduction) <repeat for other sessions>**. Please indicate your responses on the scale below:

		1 – Strongly disagree	2 – Disagree	3 – Neutral	4 – Somewhat agree	5 – Strongly agree
1	**Overall, I thought that the session was feasible to deliver as it is currently designed**					
2	**I thought that the session content was acceptable**					
3	**I thought that the session content was appropriate for trans young people**					
4	**I thought that the time allocated for the session was sufficient**					
5	**I thought that the facilitator manual provided for the session was sufficient**					

6	**What suggestions, if any, do you have for improving the session?**

Intervention overall

The following questions are about the overall TAG TEAM program. Please indicate your responses on the scale below.

		1 – Strongly disagree	2 – Disagree	3 – Neutral	4 – Somewhat agree	5 – Strongly agree
1	**Overall, the TAG TEAM program was an acceptable intervention to deliver to trans adolescents**					
2	**Delivering the TAG TEAM intervention <in-person/online> was acceptable**					

3	**Please share any thoughts or feedback about the TAG TEAM group therapy program below**

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	Available on ANZCTR
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	16
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 16
Roles and	#5b	Name and contact information for the trial sponsor	Available on

responsibilities: sponsor contact information			ANZCTR
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	16
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A – no committees
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7-8
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6-7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	2

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	10
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-13
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6-7, Figure 1, Figure 2
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9

Methods:

Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-13
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention	13

		protocols	
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A – no additional analyses
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A – no interim analyses
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			

Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A – no ancillary studies
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A – no guidelines
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental Material
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A – no biological specimens

Notes:

- 13: 6-7, Figure 1, Figure 2 The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 09. June 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai