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Evaluation of a codesigned 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 codesigned group cognitive–behavioural therapy 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 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 RCT 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 number ACTRN12623000302651, ACTRN12623000318684.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Trans Adolescent Group ThErapy for Alleviating Minority (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 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 well-being 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 a 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 well-being 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. First, based on a model of transgender affirmative CBT,[26] an uncontrolled pre–post pilot trial evaluating an eight-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 seven-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 postintervention 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 postintervention and at 3-month follow-up.[22] Another RCT evaluating an adaptation of this programme, 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 postintervention 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 programme, 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 (eg, 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 codesign study, which is being reported elsewhere (Chinsen *et al*, in preparation). Briefly, codesign is a participatory research method underscored by collaboration where consumers participate in the design of new services and products.[33] To codesign 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 codesign workshops facilitated by members of our team with experience working clinically as psychologists and conducting research with trans young people (TJC and CCP) 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 programme. Information garnered from the workshops was 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

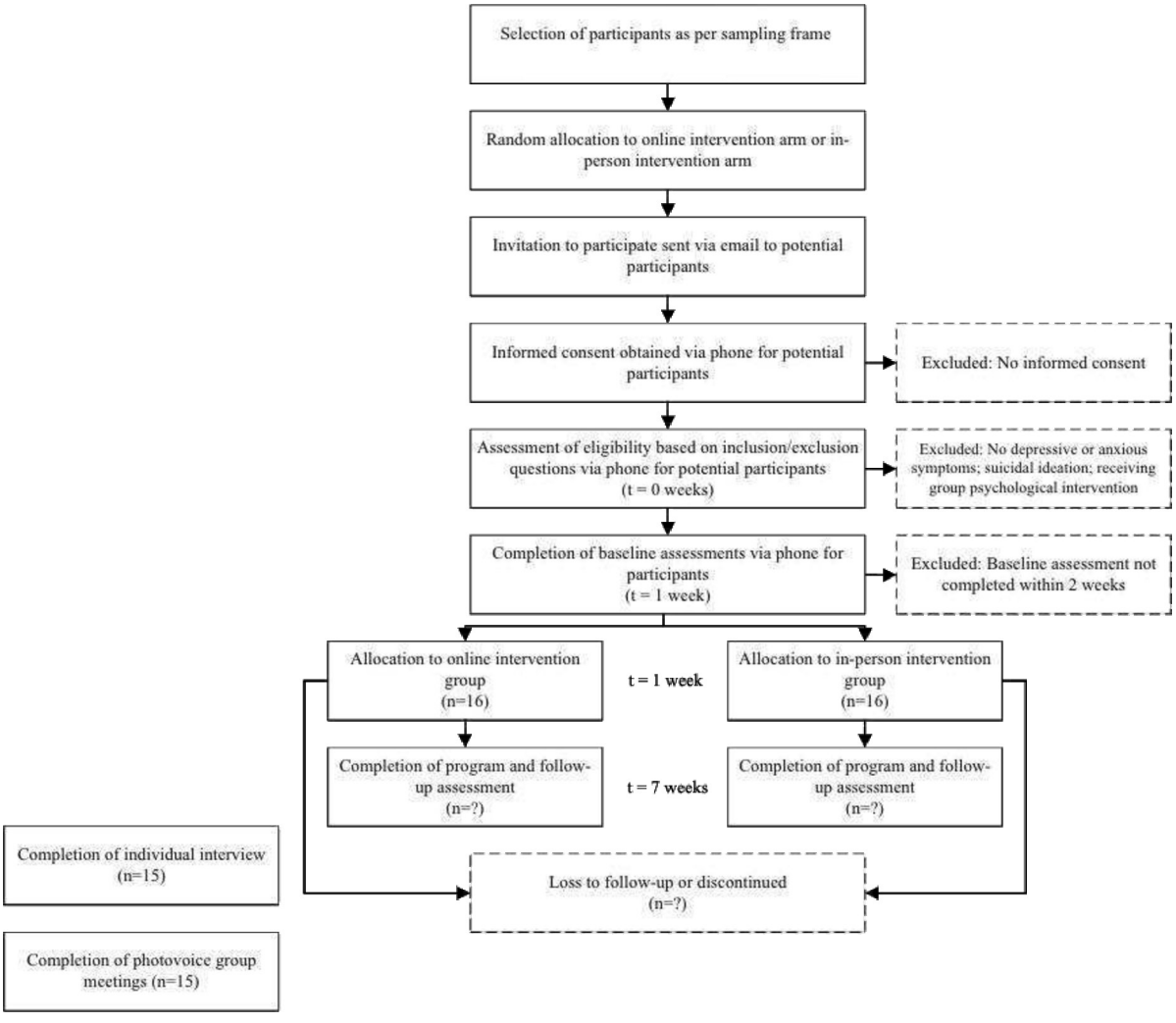

Figure 1 Flow diagram of progression of participants through feasibility trial.

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 Outcomes) 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 semistructured interviews and a photovoice study exploring their experience of the programme. 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 (eg, gender, age, race, intervention arm). In the semistructured interviews, participants will be invited to attend a 15–60 min interview that will explore their experiences of the programme 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. First, 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 programme, and their mental health before and after the programme. 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 semistructured 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 Outcomes) 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 6 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 programme 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 programme 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

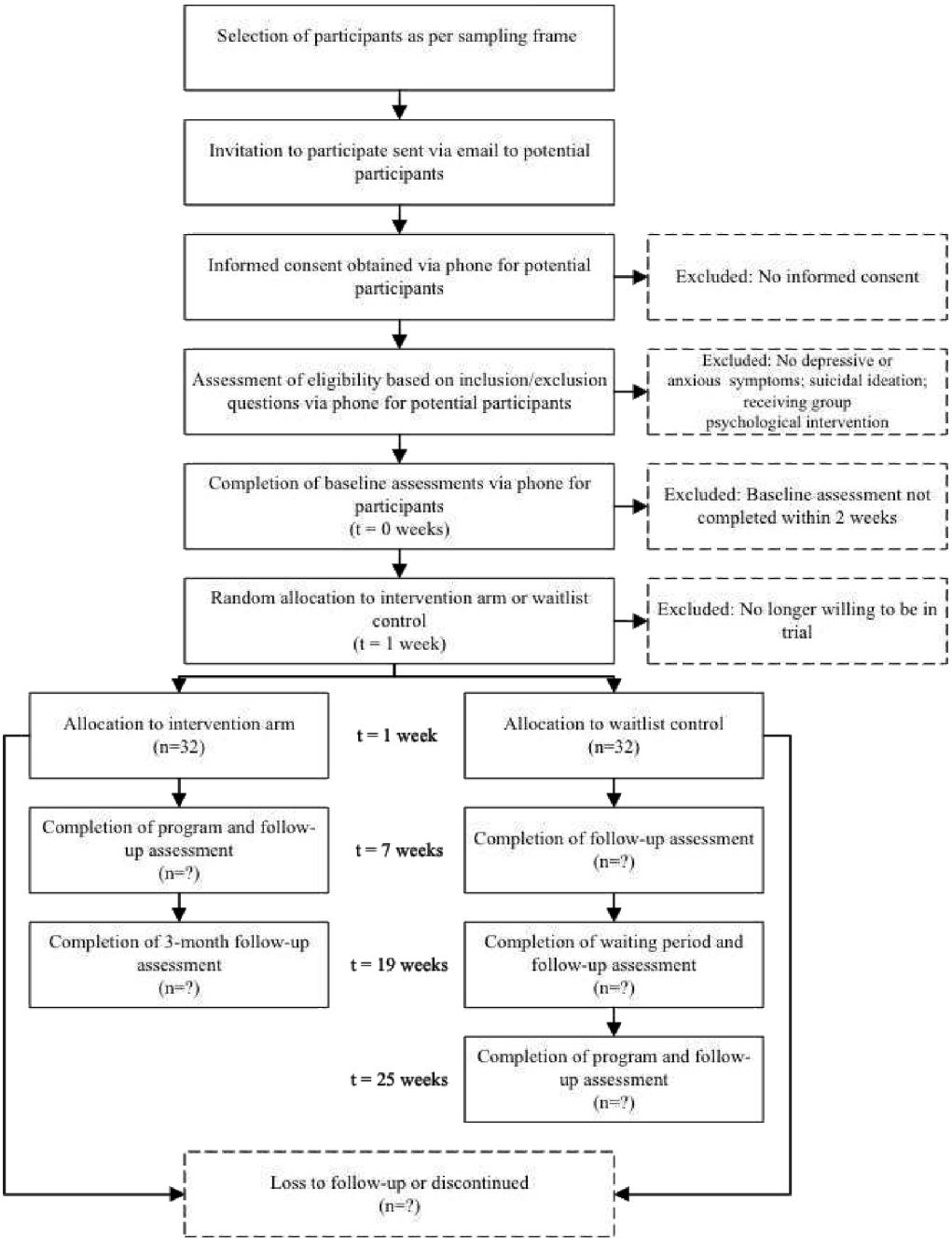

Figure 2 Flow diagram of progression of participants through pilot RCT. RCT, randomised controlled trial.

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 four groups of eight 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 (online supplemental appendix A and online supplemental 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 in 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 unblinded 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 unblinded members of the research team. The allocation will be concealed from the blinded members of the research team, and the two unblinded 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 codesign study. The intervention consists of six 2-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 (eg, 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); 5 pertain to the feasibility and acceptability of TAG TEAM itself and 5 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.

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.

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 sMFQ,[36] (2) anxiety via the SCAS,[37] (3) suicidality via the C-SSRS,[38] (4) quality of life via the Child Health Utility Instrument,[42] (5) internalised stigma, pride in gender, discrimination and community connectedness via the Gender Minority Stress and Resilience Measure for Adolescents subscales,[43] (6) gender dysphoria via the Gender Preoccupation and Stability Questionnaire,[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

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 five 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 programme (online supplemental 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 programme (online supplemental 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 (ie, 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 (ie, 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

TAG TEAM, Trans Adolescent Group ThErapy for Alleviating Minority stress.

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 SDs (or medians and IQRs 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

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 (ie, 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 (ie, 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 loss 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

RCT, randomised controlled trial.

assess and summarise questionnaire completion and intervention evaluation data.

Qualitative evaluation

The semistructured interview and photovoice group meeting data will be analysed using thematic analysis. For the interview and meeting data, we will follow Green *et al*'s analytical 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 analytical 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 codesign study where they codesigned the content, structure and format of TAG TEAM with study investigators. Next, participants in the feasibility trial will be invited to participate in semistructured 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 commenced in October 2023. The data collection for the feasibility and pilot studies is expected to be completed in December 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 codesigned 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. First, 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 codesign to develop TAG TEAM means that the content, structure and format of the programme 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 programme and their views and perspectives on the programme and its effect on their mental health.

The study also has limitations. First, the feasibility trial's small sample size may limit the external validity of the study. Second, 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, this study aims to preliminarily evaluate a codesigned 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.

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Contributors KCP, MAT, CCP, TJC and AC conceptualised the design of the study. AC drafted the manuscript. All authors reviewed and edited the manuscript and approved the final manuscript.

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Disclaimer These funders did not have a role in the conceptualisation or conduct of the study.

Competing interests KCP 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. MAT is a member of the Australian Professional Association for Trans Health and is the co-chair of its research committee. TJC is a member of the Australian Professional Association for Trans Health. CCP is a member of the Australian Professional Association for Trans Health. AC declares no competing interests.

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