

PROTOCOL

TRANSform: An Australian Longitudinal Gender Health Study

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NA

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Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH135/95).

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STUDY SYNOPSIS

Title:	TRANSform: An Australian longitudinal gender health study
Short Title:	TRANSform
Design:	Series of annual surveys
Study Centres:	University of Melbourne, Department of Medicine
Hospital:	Austin Health
Study Question:	What are the healthcare experiences and wellbeing status of transgender and gender diverse individuals?
Study Objectives:	To assess the healthcare experiences and wellbeing of transgender and gender diverse individuals and to build a dynamic community-led resource which will provide continual feedback to the community and allow longitudinal follow up of relevant health issues.
Primary Objectives:	To assess socio-economic disparities in health status, quality of life, social functioning, access to health care and possible causes and explanations.
Secondary Objectives:	Harness trans and gender diverse community perspectives to guide health service providers, researchers and policy makers to bridge the divide between clinicians, government and the community.
Inclusion Criteria:	16 years of age or older Self-identify as transgender or gender diverse Living in Australia
Exclusion Criteria:	<16 years of age Do not self-identify as transgender or gender diverse Do not live in Australia Do not wish to partake in the surveys
Number of Planned Subjects:	2000
Investigational product:	NA
Safety considerations:	Some questions relate to mental health and may cause distress
Statistical Methods:	Simple statistical methods (statistical proportions)
Subgroups:	N/A

1. STUDY SITES

a. STUDY LOCATION/S [List all locations, their address & contact details this study or parts of the study will be conducted]

Site	Address	Contact Person	Phone	Email
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Austin Health	145 Studley Road Heidelberg	Dr Ada Cheung	+61 3 9496 2260	adac@unimelb.edu. au
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2. INTRODUCTION/BACKGROUND INFORMATION

a. LAY SUMMARY

The *TRANSform* study engages trans and gender diverse people living in Australia to participate in a series of online surveys annually. The aim of the surveys is to examine healthcare experiences and wellbeing of the Australian transgender and gender diverse community and how this may change over time. This will include exploring the impact of the COVID-19 pandemic, barriers to healthcare access and the impact of gender-affirming hormones, surgery, social support and discrimination on mental and general wellbeing.

b. INTRODUCTION AND BACKGROUND INFORMATION

TRANSform is a trans and gender diverse (TGD) community-led, joint multidisciplinary endeavour encompassing an advisory board of TGD community members, policy makers, primary care, paediatrics and adult clinicians, who share a goal to achieve better health and well-being outcomes and service delivery for all TGD individuals.

It is estimated that 150,000–720,000 Australians identify as TGD, and demand for TGD healthcare is rapidly increasing(1) with a ten-fold increase in TGD individuals seeking TGD health services since 2013 (Figure 1).

Preliminary data from our study of 928 Australian TGD individuals found a highly marginalised population who are socio-economically disadvantaged and have high rates of mental illness; 86% have depression and 43% have attempted suicide. The preliminary study highlighted challenging access to medical and surgical interventions and a need for better training for healthcare professionals. Much more work needs to be done to improve health outcomes for the trans community.

Whilst investment has been made to increase the number of clinicians and services providing transgender care, little is known about satisfaction with current service providers and preferred methods of providing care. Moreover, there is minimal research on long-term health effects of gender-transition related interventions.

Initiatives to address poor health outcomes need to be informed by community perspective. Program and policy recommendations need to be based upon perspectives of community members for whom services are targeting. Traditional efforts such as community advisory groups represent the limited views of predominantly educated and articulate members. Traditional surveys from various groups can be disjointed, challenged by long turnaround time for data collection and knowledge gained is not always disseminated, peer-reviewed or translated into practice. Transgender health research has predominantly been based on those attending gender clinics which are typically based in major city centres and largely ignores the perspectives of diverse groups of TGD community members including those living in rural areas, individuals not taking standard therapies or elders who may not have access

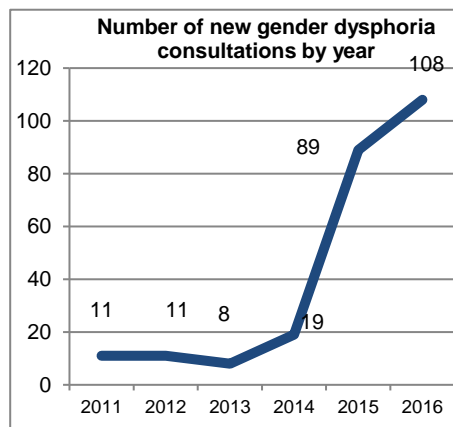


Figure 1: New presentations for gender dysphoria at Endocrine Specialist Clinic, Heidelberg, VIC

to internet. This limits an understanding of the real-world issues facing TGD community and perpetuates health disparities.

Research that engages and gives voice to the TGD community is needed – particularly community members who may be left out of traditional research geographically, to understand their perspectives on health policies and practices that impact their lives, and ultimately improve the health and well-being of Australian TGD people across the lifespan.

We will collect and analyse the views of the Australian TGD community from all walks of life in all areas of Australia, both metropolitan and remote, to understand our collective vision for the future. The study will be a tool to measure how well we are succeeding and to track wellbeing outcomes from year to year, in order to reflect the contemporary values and priorities of Australian TGD people and give the community a voice.

The overall purpose of this study is to harness TGD community perspectives to guide health service providers, researchers and policy makers in order to bridge the divide between clinicians, government and the community.

3. STUDY OBJECTIVES

a. AIMS

Overall, three general objectives are pursued by the study and within their general scope a number of more specific research questions will be of particular focus.

- 1) to build a dynamic community-led resource which will provide continual feedback to the community and allow longitudinal follow up of relevant health issues.
- 2) To assess socio-economic disparities in health status, quality of life, social functioning, access to health care and possible causes and explanations to guide improvement programs and policy development.
- 3) To assess medical and surgical interventions provided to TGD individuals and understand long-term effects and side-effects of treatments.

b. HYPOTHESIS

That transgender individuals have significant barriers to accessing healthcare

4. STUDY DESIGN

a. STUDY TYPE & DESIGN & SCHEDULE

Longitudinal mixed-methods cohort study running in 2020 and repeated annually.

b. STANDARD CARE AND ADDITIONAL TO STANDARD CARE PROCEDURES

The surveys are in addition to standard care.

c. STUDY METHODOLOGY

This study will require participants over the age of 16 years, who identify as TGD and live in Australia. After completing an enrolment survey, participants will be invited by email to participate in annual sub-surveys that are relevant to them. Participation in the sub-surveys is voluntary.

In 2020, there were three online sub-surveys. The first, focused on the experiences of the TGD community during the first three months of the COVID-19 pandemic. All participants enrolled in TRANSform were invited to participate. This provided data regarding the living situation of TGD people

during home isolation, the impact on gender-affirming healthcare, mental and physical health and support and coping strategies during this time.

In addition, in 2020 there were two optional online sub-surveys, which participants could complete, if they meet the selection criteria and want to do so. These surveys were on two highly under-researched areas; the relationships between Estradiol concentrations, risk indicators and wellbeing outcomes in trans women and trans feminine people, and pelvic pain in trans masculine people using testosterone. In addition to data generated, as part of the Estradiol survey, with additional specific consent, we will obtain copies of blood tests (identifiable) results of the individual.

In 2022, there were three sub-surveys.

The first, followed the 2020 COVID-19 survey, in exploring the ongoing impact of the pandemic on living situation, employment, mental health, gender-affirming care, community connection, and coping strategies. The 1019 participants who completed the 2020 COVID-19 survey were invited to participate.

The second sub-study was a qualitative study focused on suicide prevention in the transgender community. Participants who have reported thoughts of self-harm or suicide may be invited to participate in a one-on-one semi structured interview. The aim will be to conduct 40 participant interviews.

The third sub-study will focus on experiences of gender euphoria in the transgender community. Participation will involve completing a gender euphoria questionnaire followed by two validity measures - the Mini International Personality Item Pool and the Transgender Congruence Scale. To assess test-retest reliability, participants will be invited to complete the survey a second time two weeks later. Participation in this sub-study will contribute to the development of the first ever validated tool to measure gender euphoria. All participants enrolled in TRANSform will be invited to complete this survey.

In 2023, there will be two sub-surveys.

The first sub-survey will focus on gender identity development, disclosure of TGD identity, experiences of gender-affirming hormone therapy and surgery, and gender euphoria. All participants enrolled in TRANSform will be invited to complete this survey.

The second sub-survey will examine the facilitators and barriers to sport/fitness participation for trans and gender diverse people and explore associations between sport/fitness participation and mental health. All TRANSform participants aged 16 – 25 years will be invited to complete this survey.

The enrolment survey and all subsequent sub-surveys will be conducted using online survey platform REDCap. The qualitative study will be conducted as one-on-one interviews face to face, via videoconference (e.g., Zoom) or by telephone, depending on the most suitable mode for each participant. Each interview will be audio-recorded, and the recordings will be transcribed verbatim.

5. STUDY POPULATION

a. RECRUITMENT PROCEDURE AND FEASIBILITY

The study aims to recruit a total of 2000 TGD Australians aged 16 + at baseline.

Through active engagement with the community (predominantly online) we recruited 928 TGD people Australia-wide to participate in a preliminary pilot study over 4 months to January 2018. TRANS20 the paediatric arm, has recruited over 300 individuals. Well aware of the lack of research, enthusiasm for participation is high and approximately 600 participants in the pilot study indicated interest in ongoing participation. Participant numbers are highly feasible. Recruitment will be multifaceted with advertising online using social media targeting 106 known support groups for TGD individuals. We will also advertise at clinician offices utilising a network of health professionals via the Australian Professional Association for Trans Health. There will be particular effort directed to targeting recruitment of participants from populations that are traditionally underrepresented, such as those living outside of capital cities.

b. INCLUSION CRITERIA

Individuals residing in Australia over the age of 16 years who identify as TGD or gender diverse.

c. EXCLUSION CRITERIA

Individuals residing outside Australia, individuals under the age of 16 and individuals who do not identify as transgender or gender diverse. Any individuals not capable of providing informed consent, will also be excluded from the study.

d. CONSENT

Participation in the surveys is voluntary. At the end of each online survey, we have included eConsent through the REDCap platform. This has been deemed necessary in response to a significant number of bot/troll responses to the surveys. eConsent allows for collection of IP addresses to allow for easier recognition and removal of duplicate, bot and troll responses. No additional personal information will be collected as part of the eConsent.

e. INCENTIVES

In 2020, all participants who completed the enrolment survey received a \$5 Giftpay gift voucher. In 2021, all participants who complete the enrolment survey and one sub-survey will go into a draw to win one of fifty \$100 Giftpay gift vouchers.

To maintain engagement, we will ensure all questions are written or reviewed by a TGD committee steering the questions and secondly, we will ensure active communication with the participants will occur through regular summaries of aggregate findings.

6. PARTICIPANT SAFETY AND WITHDRAWAL

a. RISK MANAGEMENT AND SAFETY

Questions about mental health do form part of the survey and could distress some participants. Information about accessing relevant support services will therefore be included in the survey preamble. Participants will have the option to skip questions they do not want to answer and to withdraw from further involvement in the study, at any time. All questions will be optional.

b. ETHICS AND DATA CONFIDENTIALITY

The study will follow Good Clinical Practice guidelines and adhere to all ethical requirements.

7. STATISTICAL METHODS

a. SAMPLE SIZE ESTIMATION & JUSTIFICATION

Approximately 2000 TGD participants enrolled in TRANSform in 2020. We estimate that this will provide significant representation of the community to have meaningful results.

b. STATISTICAL METHODS TO BE UNDERTAKEN

Simple statistical methods such as statistical proportions will be used to analyse the quantitative data. Free text responses in the survey will be thematically coded using NVivo qualitative analysis software.

8. DATA SECURITY & HANDLING

a. DETAILS OF WHERE RECORDS WILL BE KEPT & HOW LONG WILL THEY BE STORED

Raw data will be stored for 7 years on a password-protected area of the University of Melbourne Server.

b. CONFIDENTIALITY AND SECURITY

All data is non-identifiable and will be stored for 7 years in a password protected University of Melbourne server. Only investigators will have access.

9. SIGNIFICANCE

This will be the only TGD-led longitudinal community cohort study of its size worldwide. Due to a profound lack of research in transgender medicine to guide clinical care, we will deliver evidence-based improvements to outcomes, to allow the design of appropriate care services for TGD individuals living in Australia. Data obtained will be strategically communicated, not only in scholarly publications but also in forms relevant to policymakers and community members.

Based on the most conservative estimates, TGD people outnumber those living with breast and prostate cancers. Yet searching clinicaltrials.gov reveals only 135 current studies in TGD persons, compared to over 8,000 for breast cancer and 4000 for prostate cancer. The disparity is unmistakable. The study will stimulate and engage community discussion about the types of policies, programs, and activities that would push us towards achieving the best possible quality of life, health and well-being for the TGD community now and into the future. Furthermore, it will inform policy by helping policy shapers and decision makers to understand community perspectives and the consequences of their actions.

Much needed knowledge will be gained on long-term effects of gender affirming treatments, so that optimal strategies and programs can be developed to mitigate risk, to inform health service delivery and guide safe and effective clinical treatment pathways. This is important given the rising number of individuals seeking healthcare and treatment is typically started young and continues lifelong. Many medical diagnoses are sex hormone dependent and may have higher prevalence amongst TGD individuals on hormone therapy, including neurodevelopmental conditions(2), thromboembolic disease(3), cardiovascular disease(4), hormone-dependent cancers(5), osteoporosis(6), autoimmune disease(7), neurodegenerative disease(8), and dry eye disease(9). Results will embed research evidence in healthcare policy and practice improvement, where current treatment practices vary widely, and efficacy is mostly anecdotal. This facilitates evidence-based care, efficient use of resources and supports decision making in treatment options for clinicians and patients.

Australia is uniquely positioned, as societal acceptance has led to a rapid increase in demand for transgender health services in the last 5 years and we have access to innovative health service delivery including state-of-the-art research platforms and groups. This study will provide real world clinical data on health outcomes of transgender individuals, not just isolated to those from hospital clinics on strict treatment protocols, as in European registries and will be a landmark cutting-edge TGD-community led initiative.

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