Study Protocol

Title:

YOUNG PEOPLE DISTRESSED BY GENDER DYSPHORIA: A QUALITATIVE STUDY EXPLORING THE PERSPECTIVES OF YOUNG PEOPLE, PARENTS/CARERS AND CARE PROFESSIONALS

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1 Plain English Summary

Some children and young people can experience significant levels of gender-related dysphoria/distress in their course of their development. This distress is said to arise from a persistent mismatch between a young person's felt gender identity and the sex they were registered/assigned at birth[1].

The numbers of children and young people referred to the Tavistock and Portman's Gender Identity Development Service (GIDS) - the only NHS funded service for young people with gender-related dysphoria/distress in England and Wales - have risen markedly over the last decade, resulting in lengthy waiting times and uncertainty for young people and their families. There is also a limited (and contested) evidence base, with which to inform current or future provision. Consequently, there is an important need to understand the needs and experiences of this changing population, identify the different management options and assess outcomes.

This qualitative study is part of a programme of research (including a series of systematic reviews and epidemiological analysis of existing datasets) to inform an independent review of gender identity development services for young people, reporting to NHS England and led by Dr Hilary Cass (https://cass.independent-review.uk/).

The research explores how young people, their parents and young adults experience gender-related dysphoria/distress. The study will specifically explore how young people negotiate and express their distress; examine their - and their parents' - views on referral, assessment and possible interventions and treatment; and investigate the perspectives of care professionals who offer support.

This study will use a qualitative methodology, to purposively sample and interview 40 children and young adults between the ages of 12 and 30 years old, with a diverse range of experiences and outcomes. From the interviews with children and young people the study will purposively sample 20 parents and 20 care professionals.

Thematic analysis will be used to examine interview material, identify themes and explore the potential for optimal care consistent with the experiences of young people and their families.

2 Background

This qualitative enquiry focuses on understanding the experience of children, young people and their families when making sense of - and negotiating - gender-related dysphoria/distress. This requires exploring how children and young people interpret, understand and respond to their experiences, within their day-to-

[1] The research team acknowledge that there are debates about terminology (see Bloom et al., 2021). Our PPI activities have discussed this and we have sought advice on the project title. Tensions, however, remain between offering an evaluation of current health service support for children and using medical categorisation to pathologise transgender experience. Our fieldwork with young adults, for example, is likely to include those who no longer regard themselves as having gender-related distress. Medical classification is also changing, with ICD11, likely to replace gender dsyporia (and its association with mental health) with gender incongruence. The research will remain sensitive to these changes.

day lives (Riessman, 2009). It also requires engaging with a diverse range of different experiences and understanding the variety of pathways taken by young people and their families (see Langton et al., 2018).

In designing our qualitative approach, the research is sensitive to the clinical context, in which support is offered (see de Graaf and Carmichael, 2019), particularly since this is an important component of the CASS review. This, however, is not without its challenges, especially given the contested nature of current debates (see Faye, 2021). Divergent positions occur and clinical practice reflects a lack of consensus about how to conceptualise and respond to gender-based distress (Katz-Wise, et al., 2018; Ehrensaft, 2017).

The '*watchful waiting*' approach, for example, argues for close assessment and observation of the child's sense of gender identity, relative to their development (see Zucker et al. 2017). While recognising the importance of medical interventions and social transitioning, this approach only advocates their use when a young person's distress continues to escalate with the onset of puberty and/or as they develop (see Medico et al., 2020). By contrast, the '*gender-affirmative*' model recommends that parents and care professionals offer early acceptance and actively affirm the child's feelings (see Olson-Kennedy, 2016, Chen et al., 2016). The primary decision maker is the child (Kozlowska et al., 2021) and the role of services is to facilitate access to social transitioning and medical interventions (Ehrensaft et al., 2018). There are, however, those who believe that the potential outcomes associated with childhood gender-related dysphoria/distress are more wide-ranging and fluid. They propose a more '*explanatory*' approach, which advises against affirmation and argues for robust and careful decision making, sensitive to this possible fluidity. The testimonials of those who wish to detransition have introduced additional and recent complexity to how best to meet the needs of young people (see Butler and Hutchinson, 2020). In response to this complexity, some care professionals to highlight the importance of in-depth assessment (Churcher-Clarke and Spiliadis, 2019), including the need for exploratory psychosocial support that seeks to understand a range of connected factors in young people's lives, which may be contributing to the emergence of gender-related dysphoria/distress (see Kozlowska et al., 2021).

Children and their families, in addition to making sense of – and giving meaning to - their own feelings, have to negotiate and understand these divergent clinical perspectives on how to proceed (de Graaf and Carmichael, 2019; and see Lancet Child and Adolescent Editorial, 2021). It is, therefore, important to ensure their voices are not lost in the process (Vidal-Ortis, 2008), particularly given a lack of current evidence, consistent with diverse experiences, in a rapidly changing cultural context (Hines, 2019). This is further reflected in the challenges of providing accessible and appropriate care (Butler et al., 2017); changes in birth-registered sex ratio, which now include more females than males (Aitken et al., 2015); possible over-representation of young people, who have a diagnosis associated with an autistic spectrum condition (Van Der Miesen, 2015); and debated uncertainties about long-term outcomes (de Vries et al, 2011).

Qualitative approaches are particularly effective in exploring complex, sensitive and potentially contested themes (Riessman, 2009). The qualitative research will engage with the young person's broader biographical and lived experience and use this as the basis to explore how gender-related dysphoria/distress is defined, articulated and negotiated, over time, within the context of family and social networks (see Gergen and Gergen, 2006). The research will include a range of experiences, at different time points, including those who are at the initial stages of expressing gender-related dysphoria/distress, following a referral to GIDS; those exploring and pursuing different treatment options; and young adults, who are further along the process of resolving their distress.

2.1 Aim and Objectives

Aim: To explore how children, young people and young adults experience gender-related dysphoria/ distress and negotiate the potential incongruence associated with expressing a gender identity different to their sex, registered/assigned at birth.

Objectives:

1. To explore how children, young people and young adults understand, respond and negotiate gender-related dysphoria/distress and discomfort within the context of their social networks;
2. To examine the perspectives, understandings and responses of parents (or carers), including how they support their child;
3. To investigate how children, young people, young adults and their families experience and negotiate current referral, assessment and possible treatment and intervention options within the national specialist service referral, assessment and (possible) treatment;
4. To understand the role and experiences of care professionals who offer support, including identifying shared and potentially divergent views of what constitutes optimal care.

3 Study design

This is a qualitative study of children and young adults' experiences of gender-related dysphoria/distress and of parents and care professionals' experiences of the referral, assessment and treatment pathways currently open to them. It aims to identify the different models of care provided to children and young adults and explore barriers or facilitators to providing this care.

3.1 Setting and participants

There will be three groups of participants in this study:

- Children, young people and young adults who have experienced gender-related dysphoria/distress
- Parents of children and young people who are experiencing gender-related dysphoria/distress; and
- Care professionals who work with children and young adults with gender-related dysphoria/distress.

3.1.1 Children, young people and young adults who have experienced gender-related dysphoria/distress

The study will include ~ 40 children, young people and young adults. Theoretically informed purposive sampling will be undertaken to include an even number of young people identifying as men and women, in addition to ensuring that experiences are sought from a diverse range of ethnic and social backgrounds.

The sample will include children, young people and young adults who are at different stages of resolving their gender-related dysphoria/distress. It will include young adults (aged 18 to 30 years old) and children and young people (aged 12 to 18 years old). Our different approaches to recruitment reflect these different stages (see p6 below).

Twenty children and young people (aged between 12 and 18 years old) currently negotiating the process of distress, will be recruited via their contact with healthcare provision, which is likely to be through GIDS, although to ensure diversity, some children and young people will be recruited through non-GIDS provision. The theoretical sampling frame will include children and young people:

- at the initial assessment stage of engaging with the national specialist service where no decision about support pathways or medical intervention has been made;
- who have been referred to the GIDS endocrine clinic and prescribed hormone blockers and/or cross-sex hormones;
- for whom physical interventions are not considered to be the next best step which may include factors associated with concerns over a child's capacity to consent, lack of parental consent, clinician caution and/ or other associated difficulties that mean a decision is not currently possible; and
- those whose gender-related dysphoria/distress is resolved because of range of factors including ongoing assessment, psycho-social exploration and discharge back to GP or local support services.

Twenty young adults (aged between 18 to 30 years old), who are much further on in the process of negotiating their gender identity, following distress during childhood, will be recruited via voluntary organisations and in rare circumstances, social media. The use of a theoretical sample will help reduce potential biases and include those who have:

- made a medical and social gender transition;
- used psychological and/or social explorations but not medical transition;
- continue to identify as transgender but do not wish to access medical interventions;
- resolved gender dysphoria without accessing GIDS or adult gender service; and
- made a medical transition (including hormonal and/or surgery) and since detransitioned or considering detransitioning.

We will monitor recruitment to ensure that we are seeing a spread across these key characteristics and to ensure ethnic and social diversity.

3.1.2 Parents

Following analysis of the interviews with young people we will recruit parents/carers. Purposive sampling will be undertaken to select parents/carers identified through the interviews with children and young people (aged between 12 and 18 years old), currently in contact with or recently discharged from GIDS. These will include parents who hold a range of views and experiences.

In order to capture the diversity of perspectives, we anticipate that a sample of 20 parents of children expressing gender-related dysphoria/distress will be required. We will explore dyads that explore experiences of both mother and father along with including a diverse range of family organisation, including single parents, those where parents no longer live together, adopted parents/guardians and looked after children.

3.1.3 Care professionals

Analysis of first phase interviews with young people will identify care professionals whom the child and/or parent - currently in contact with or recently discharged from GIDS - identified as important, along with key strategic professionals known to support young people experiencing gender-related dysphoria/distress. We aim to generate a sample of 20 care professionals, from a variety of different backgrounds, including health and social care, education and those working in voluntary or third sector organisations.

3.2 Recruitment

We will be recruiting three groups of participants.

3.21. We will purposively recruit 40 children, young people and adults, aged 12 to 30 years old. Twenty of these will be aged 12 to 18 years old and recruited through the NHS Gender Identity Development Services (GIDS) and - to ensure diversity consistency with our sampling frame - via voluntary organisations. Parents will consent their child into the study - if under 16 years of age - and assent to participate sought from the child. Young people aged 16 to 18 years old will consent themselves.

Clinical and other care staff, working to an agreed, defined sampling framework (see p5 above), will discuss the study with parents of potentially eligible participants, who they see/speak to in consultations (including face-to-face or virtual), meetings and visits, and provide them with the study information pack. This information pack will contain an invitation letter, participant information sheets (including assent information for children), a consent-to-contact (CTC) form for parents and a return envelope addressed to the study team. The CTC form will include the young person's name, preferred gender, contact details and statements of parental consent and assent for the study team to contact the child. The CTC form can either be completed with the parent at the time of providing the pack/discussing the study (and securely uploaded by the member of staff to the study team) or be taken away by the parent to complete and return by post, email or via a telephone call/virtual meeting with the study team. The study team will contact all families who complete a CTC form to discuss the study and whether they still wish their child to take part, check eligibility, and if appropriate, take informed consent from parents and assent from children/young people to participate before any interview. Informed consent will be written or recorded virtually. We are aware consent/assent may involve discussion and negotiation with families and will remain sensitive to family dynamics, when negotiating access to the study.

Twenty young adults (aged 18 to 30 years old) will be recruited largely via voluntary/third sector organisations and occasionally, by social media, in accordance with purposive sampling frame. They will be provided with a study information pack by the voluntary organisation they are in contact with; and will be asked to complete the consent-to-contact form and return it to the study team via post, email or telephone call. Social media sites such as Facebook pages and Twitter will only be used if the study is unable to recruit a sufficient diverse sample from community organisations. Participants who respond to these recruitment posts and are interested in taking part in the study will be directed to the chief investigator. They will be provided with an information pack about the study. Before the interview begins, participants will be asked to complete the consent form and return it to the study team via post, email or telephone/virtual call. For those who contact us and do not fit our sampling criteria, we will explain why not and offer to send them a summary of the study findings.

3.22. We will purposively recruit 20 parents who have children experiencing gender-related dysphoria/distress and who are currently or have been recently discharged from GIDS. We will identity these parents through the interviews with children/young people and the sample will select a range of different experiences (see p6 above). Consent to contact their parents will be sought from the child. (Those children who do not wish the study to consent their parents, can still participate in the research). No details of the child's experience will be discussed during the interviews with parents. Nor are parents obligated to take part in the study because their child has. Parents will be provided with an information pack about the study and invited to talk about it with a member of the research team, they will be asked to complete the consent form and return it to the study team via post, email or via a telephone/virtual call.

3.23 We will purposively recruit 20 care professionals whom the young person and/or parent has identified as important, along with key strategic professionals known to support children experiencing gender-related dysphoria/distress. Contact will be discussed with the child or parent and their permission sought to contact the professional, if involved in the care. To protect confidentiality, no individual details will be discussed with these care professionals. The interview will focus on their general experience of responding to those who question their gender identity. Key professionals for interview will be identified via email contact. Snowball sampling from these initial interviews will identity further professionals. Participants will be invited to participate in this study via email with a participant information sheet and electronic consent form attached. The key professional will be asked to reply to the email to book an interview at a date and time convenient to them. One reminder email will be sent 14 days after initial contract if no response.

3.3 Data collection

3.3.1 Children, young people and young adults

We will conduct telephone or video calls or face-to-face interviews semi-structured interviews, depending on participant's preference. We will aim for the interview to last between 45-60 minutes in a setting of the participant's choice. Participants will also be given a choice where possible over the gender of the interviewer. Before the interview starts, written or recorded informed consent (separate from the interview recording) will be obtained. With consent, the interview will be recorded digitally and transcribed verbatim.

A guide, initially developed from the literature and discussions with young people, will be used to ensure that the interviews cover similar topics (see attached). Interviews will be used to understand how young people interpret and create meaning from their social experience. The interviews will explore the expression of their gendered identity and how this has evolved over time; the extent they feel 'distress' and are able to express this 'distress'; how their social networks, (family, school, peers) response to and influence their gender expression; the support of professionals in assessment and treatment, including identifying potential barriers/facilitators to appropriate and accessible care; the extent children and young people are content with their current options and feel they are being listened to; and their future aspirations.

To help support children and young people to articulate their experience - and if the child or young person chooses to - we will provide them with a digital camera and encourage them to produce photographs that express who they are. This approach can sometimes help young people discuss their experience (Woodgate, 2016). These photographs will only be used during the interview as an aid to facilitate discussion and will not be reproduced in any form or appear in any publications. The aim and process involved in the use of photographs will be discussed with young people during recruitment. Young people, however, are under no pressure to do this. It is their choice. Any photographs used will remain with the young person.

3.3.2 Parents

Following analysis of the interviews with young people we will recruit parents/carers. Purposive sampling will be undertaken to select parents/carers identified through the interviews with children and young people (see p6 above). To capture the diversity of perspectives, we anticipate that a sample of 20 parents of children expressing gender-related dysphoria/distress will be required. We will explore dyads that explore experiences of both mother and father along with including a diverse range of family organisation, including single parents, parents who no longer live together, parents/carers of children who are adopted or in care.

The interviews with parents will explore: their initial responses to their child's questioning of their gender identity; negotiations with their child and other family members, including the challenges they believe their child faces; the support given to their child; and their relationship with professionals. We will not however, discuss their child's experience (or that of the other parent, if included). Parents will be interviewed once, in a location of their choosing and the interview will last approximately 60 minutes. Before the interview starts, written or recorded informed consent (separate from the interview recording) will be obtained. With the participant's consent, the interview will be recorded digitally and transcribed verbatim.

3.3.3 *Care Professionals*

Analysis of first phase interviews with young people will identify care professionals whom the young person and/or parent has identified as important, along with key strategic professionals known to support children with doubts about their birth registered sex.

We aim to generate a sample of 20 care professionals, from a variety of different backgrounds, including health and social care, education and those working in voluntary or third sector organisations.

Individual interviews with these professionals will encourage them to reflect on their practice, by exploring what they see as the main challenges facing young people and their families when negotiating gender-related dysphoria/distress, the support they are able to offer and the extent they feel young people are able to make appropriate choices. We will not be discussing individual children or parents' experiences but use the interview to get the care professional to reflect on their general experience. Interviews will specifically explore the constraints practitioners operate under and the ethical dilemmas they face, in addition to potential opportunities they identity in supporting children and young people. This will help us focus any policy guidance.

Each care professional will be interviewed once for approximately 60 minutes. Before the interview starts, written or recorded informed consent (separate from the interview recording) will be obtained. With the participant's consent, the interview will be recorded digitally and later transcribed verbatim.

3.4 Analysis

The interview material from children, young people, and young adults, parents and care professionals will initially be analysed separately but using the same methodology of thematic and narrative analysis (see Hollway and Jefferson, 1997). Atlas.ti (version 5.2) for managing and coding data.

Interviews will be audio-recorded (with respondent's consent), transcribed and organised according to analytical headings. During the analysis, regular meetings will be held between the research team to discuss the emergent themes from the fieldwork material. The analyses will be an iterative process, with some steps repeated if necessary.

- Familiarisation: interview transcripts will be thoroughly read to familiarise with the data.
- Generating initial codes: data will be systematically coded across all the transcripts, identifying all data in relation to each code. The context and relationship between codes will be important, given the complexity of the issues facing young people with gender-related dysphoria/distress.
- Theme development: codes will then be collated into potential themes. Comparison between the different accounts will be undertaken to clarify the recurring themes.
- Reviewing themes - themes will be checked across the entire dataset to produce a thematic map.
- Thematic Analysis: during this phase the key features of each theme will be specified and clearly defined and named.

- Writing up: the final stage of analysis will summarise the themes with examples from the data.

The focus of the combined analysis will be to connect the accounts of young people, their parents and care professionals regarding the experience of gender related distress and specifically explore how young people' voices are heard, understood and responded to; how relationships between these parties are negotiated; and what optimal care would look like (see Elman, 2009).

We will use several methods to enhance the quality of analysis. A second researcher will code 20% of the material. Preliminary findings will be discussed and interpreted with the wider research team, the study advisory panel and representatives of our participants' panel of young people to help credibility (truth validity) and authenticity (that findings represent a range of different perspectives). Analysis will be carried out by the research team. Interview material will be stored at the University of York.

3.5 Outputs

Outputs from this study will include information regarding the future models of care for children experiencing gender related distress. This will inform the CASS review (see above) and includes identifying key indicators to assess the quality of care from the different perspectives of young people, parents and care professionals. We will ensure the maximum distribution of summary documents and make them available to various professional and community organisations, with an interest in this area. The project will also generate peer reviewed publications in high ranking and relevant journals (such as Social Science and Medicine, Sociology of Health and Illness, British Medical Journal, Archives of Disease in Childhood, Journal of American Medical Association Pediatrics); articles in professional orientated and other relevant publications (e.g., RCPCH, RCGP); presentations at academic conferences, professional meetings and community workshops. At the end of the project, we will organise a day conference, organised in partnership with key stakeholders, in which we launch and discuss the findings of the project.

4 Study management

4.1 Study team

Professor Karl Atkin

Professor Lorna Fraser

Dr Trilby Langton

Dr Claire Heathcote

4.2 Sponsorship

University of York

4.3 Funding

NHE England

5 Governance and ethics approval

The study will be conducted to protect the human rights and dignity of the participants as reflected in the 1996 version of the Helsinki Declaration. Explicit wishes of the participant will be respected including the right to withdraw from the study at any time; the interest of the participant will prevail over those of science and society; informed consent will be obtained; provision will be made for indemnity by the investigator and sponsor; and a contact name for further information will be provided.

The study will adhere to the ethical guidelines provided by the Social Research Association (https://www.the-sra.org.uk). This provides a framework for ensuring the physical, personal and emotion safety of participants and researchers. We will seek formal ethical approval under medical research and ethics committee (MREC) guidance, addressing issues concerning informed consent, participant burden, participant confidentiality, data management and researcher safety, as summarised below.

Team members will have an enhanced CRB check and we will comply with all guidance issued as part of the Government sponsored Vetting and Barring Scheme.

5.1 Informed consent

Children and young people will be consented according to their age (see attached diagram for different approaches). For those under 16 years old, parental informed consent and child assent will be sought. Informed consent will be sought from those over 16 years old. Informed consent will be sought from parents, interviewed as part of the study and care professionals.

A specific participant information sheet will be provided to the different groups of participants (children and young people, parents consenting their children, young adults, parents interviewed as part in the study and care professionals). Informed consent and assent will be obtained by the researcher before any interview commences (also see above). We have discussed consent and assent materials, sampling strategy, interview topics and participation information sheets with PPI representatives. These including children and young people, who are questioning their identity along with young adults, who have resolved this questioning.

The children and young people we interview will have expressed distress about their gender identity. We will, therefore, remain sensitive to ensure they fully understand what participation in the research entails. This is likely to require additional negotiation, in order to ensure the child and young people is entirely comfortable with taking part in the research, irrespective of their parent's consent. Negotiation will also occur between the research team and their child's parents. This includes having discussions about the research process and the expected role of their child. We would not wish for the research to undermine any relationship between a parent and their child. The need for this negotiation will be mentioned in the information sheets.

5.1.1 Sample of children, Young people and young adults

For children aged between 12 and 15 years of age, parental consent and child assent will be obtained before the start of the interview.

Young people (aged between 16 and 17 years old) and young adults (aged between 18 and 30 years old) will be required to give formal consent prior to the start of the interview.

Before beginning the interview, participants will be reminded that consent will not affect present or future contact with support agencies and that they can withdraw from the study at any time, without giving a reason. The interviewer will also outline how a participant's data will be stored and that the researchers will respect the participant's anonymity and confidentiality. This includes not disclosing what they say to their parents or care professionals.

Consent will be monitored throughout the interviews (e.g., looking for disengagement or withdrawal, checking that they are happy to continue); and participants will be reminded that they can choose not to answer questions that are too distressing or that they would prefer not to answer.

With children aged between 12 to 15 years of age and over, the study will use a two-stage consent/assent process. First, parents of potential participants identified by through GIDS will be told about the research by a GIDS team member and given or sent an information pack (see p6 above). If they are interested to take part, parents will be asked to complete and return the 'consent to be contact form' to the research team. A parent can also choose to ask the care professional to complete this on their behalf. Once the research team receives this form, a researcher from the team will contact the parents to explain and further discuss the study. If the parents provide consent to continue, assent will be sought from their child.

The research team will ensure the parent and their child fully understand the aims of the research; and are clear about what participation involves before an interview begins. Both the researcher and the parent will confirm that consent has been obtained prior to the start of interviews. This may have to be done virtually, but in all cases formally recorded (and separately from the interview recording). The participant will receive a copy of this consent, which will also be filed in the Investigator Site File (ISF).

If child - or their parent, who provided consent - chooses to no longer take part in the study, they will be able to withdraw their - or their child's information - as long as it has not already been used in the study (i.e., for analysis). No further data will be collected from and all data able to be withdrawn (from their contribution) will be destroyed unless consent is provided to include data collected up to the point of withdrawal in the study.

In addition, children and young people between 12 and 16 will be asked (in a separate part of the assent process) if they consent to the research team contacting their parents to be involved in the study. It is not necessary for the young person to agree to their parents' participation in order to take part in the research.

For those over 18 years of age, a single stage consent process will occur. A voluntary or community organisations will discuss the research with potential participants, provide a study information pack and ask the participant to complete a 'consent to contact' form and return to the research team. The research team will contact the young adult and formally gain consent before beginning any interview. Those wishing to take part following contact via social media, will be assessed according to the study criteria and if eligible sent a study information pack and invited to contact the research team if they wish to take part in the research. Formal consent will be obtained prior to any interview. This may have to be done virtually, but in all cases recorded (and separately from the interview recording). The participant will receive a copy, which will also be filed in the Investigator Site File (ISF).

5.1.2 Parental sample

As part of the consent process, the research team will ensure that all parents understand the study, including why they are being asked to participate and what would be involved if they agree to participate; confirm that parents will be able to withdraw from the study at any time (including after the interview has been completed);

reassure them that consent will not affect present or future contact with support agencies. The research team will also outline how their data will be stored and how the researchers will respect the participant's anonymity and confidentiality. Parents can refuse to participate, irrespective of their child's consent to contact them. Formal consent will be obtained prior to the interview. This may have to be done virtually, but in all cases recorded (and separately from the interview recording). The participant will receive a copy of this consent, which will also be filed in the Investigator Site File (ISF).

Consent will be monitored throughout the interviews (e.g., looking for disengagement or withdrawal, checking that they are happy to continue) and participants will be reminded that they can choose not to answer questions that are too distressing or that they would prefer not to answer.

Participants will be informed of their right to withdraw at any time and without giving a reason.

If a participant chooses to no longer take part in the study, they will be able to withdraw their information as long as it has not already been used in the study (i.e., for analysis). No further data will be collected and all data (associated with their contribution) destroyed unless consent is provided to include data collected up to the point of withdrawal in the study.

5.1.3 Care Professionals

The same process as outlined in 5.1.2 will be followed with Care Professionals who will be provided with a consent form. This may be recorded virtually. The participant will receive a copy of this consent, which will also be filed in the Investigator Site File (ISF).

5.2 Participant burden

5.2.1 Children, young people and young adults

Young people and parents may feel coerced into participating in the research. We will minimise this by emphasising that participation is completely voluntary and that refusal to participate will in no way impact on access to care.

There is a risk that young people will find discussing the subject of gender related distress upsetting. Participants will be made aware of the topics to be discussed in advance, in the participant information sheet.

Interviews will be conducted by researchers experienced at conducting sensitive interviews. They will assess for distress before and throughout the meeting, offering to pause or stop the interview at any time. At the start participants will be reminded that they can stop the interview, or withdraw from the study at any point, and without giving a reason. If necessary, the researcher will help the participant identify suitable sources of support for them following the interview. Instances where the research believes there is a risk to wellbeing (or potential harm) will be discussed with a member of the research team, Dr Trilby Langton – a clinical psychologist, with over ten years of experience of supporting children who experience gender distress - and an assessment made about onward referral.

There is the risk that participants may feel unable to speak freely about GIDS services due to concerns about the possible impact on their care. We would, therefore, emphasise that confidentiality and anonymity of the interview process and the confidentiality would only be broken if they disclosed something that indicated harm to themselves or someone else (see below). We will specifically emphasise that what they say, will not be shared with their parent or care professional.

5.2.2 Parents

Parents may find discussing the subject of gender related distress upsetting. Participants will be made aware of the topics to be discussed in advance in a participant information sheet for parents.

Similar to interviews with children and young people, researchers will assess for distress before and throughout the meeting, offering to pause or stop the interview at any time. Parents will be reminded that they can stop the interview, or withdraw from the study at any point, and without giving a reason. If necessary, the researcher will help the participant identify suitable sources of support for them following the interview.

The impact participation might have on the care received by their child may be of concern to parents. We will emphasise participation is completely voluntary and that refusal to participate will in no way impact on their child's access to care. We would also emphasise that confidentiality and anonymity of the interview process. This includes emphasising that nothing they tell us, will be shared with other family members or care professionals.

5.2.3 Care Professionals

Participation in research on this politically contested topic may cause reputational concern among care professionals. In order to provide reassurance in relation to our aims and methodology we will provide an accessible protocol, available to stakeholders. It is possible that the professionals recruited may feel pressured to participate. They will be informed that the decision about whether to participate is voluntary and will not impact them in any way. The research team will emphasise the confidentiality and anonymity of the interview process. To reduce the burden on care professionals we will be flexible about the date and time of the interviews and limit these to 45 minutes.

5.3 Participant confidentiality

Participants will be informed of their right to confidentiality, and also what this means if they disclose information that suggests that they or others are at serious risk of harm. Participants will also be informed that they have the right to withdraw from the study at any time, and to exclude their material from the study if not already analysed as part of the research. All personal data will be stored in a password-protected files, using a participant identifier to link participants' details to their data (i.e., interview transcript). This information will not be accessed by anyone outside of the research team. Quotations from participants may be used in research reports and other publications and presentations. However, care will be taken to protect the anonymity of participants – and the organisations they work for - so that others are not able to identify them.

It will be important in this study to ensure absolute confidentiality within and between interviews, particularly since we are talking to children and young people, their parents and care professionals who may be offering support to the child and young person.

Participants will be made aware that the only time the research team would break then duty of confidentiality is when they had concerns about the participant harming themselves or others. This would be discussed with the participant and advice sought from Dr Trilby Langton (see p13 above).

5.4 Data management/Data protection

All participant data will be handled in line with the 2018 General Data Protection Act and the Research Governance Framework for Health and Social Care Research. Anonymized interview transcripts and field diaries will be securely archived by the University of York for a minimum of ten years. Personal data of participants will be stored for up to three years after the study has ended for the purpose of dissemination of

study findings. It is unlikely that this will take longer than 12 months, however, to ensure that participants receive adequate and full information about the study after it is complete, additional time has been allocated.

Information collected during the study will be kept strictly confidential and held securely on paper and/or electronic formats. The research team will comply with all aspects of the 2018 General Data Protection Act and operationally this will include obtaining consent from patients and carers to record personal details including name, postal and email address, and contact telephone numbers; and appropriate storage, restricted access and disposal arrangements for patient and carer personal details. All participants will be anonymised at the point of consent, by assignment of a study identifier code. Personal data and pseudonymised data will be stored separately in a restricted access folder on a secure university server and access will be password protected.

All data will be stored in accordance with data protection requirements and will be kept either in a locked filing cabinet in a secure office or in the case of electronic data on a secure server with a password protected computer and files.

Participants' names and contact details will be stored electronically on a password protected file on a secure server and only accessed by the research team. Electronic data will be stored on password-protected secure computers in the research team members' locked offices.

Audio recordings of the interviews will be downloaded onto a password protected computer and deleted from the recording device.

No data will be stored on a home computer or laptop.

5.5 Researcher safety

To ensure researcher safety, we will adhere to the University of York policy and procedure on lone working and employ a buddy system to monitor researchers' whereabouts and safety when visiting participants. Counselling will also be available.

5.6 Study oversight group

An Independent Advisory Board/Study Steering Committee with representation from all the key support organisations, academic input, and young people and parents will meet every six months. They will report to the Assurance Group responsible for oversight of the CASS review (see p3 above).

6 Patient and public involvement

We will work closely with the CASS Independent Review Team throughout this study to ensure that the membership of the patient and public involvement group includes those with a wide range of experiences and outcomes in relation to their gender. This may include offering additional support and training to ensure children, young people and their parents can meaningfully and confidentiality engage with the project.

Young people and young adults who have experienced gender-related dysdistress have been/will be involved in the study in several ways, including: discussing title of project and logo; the protocol; design and content of participant information sheets; membership of the steering group; development of the topics to discuss during interviews; interpretation of findings and the design and content of children and young person-facing research summaries.

There will be ongoing community engagement: throughout the project we will engage with different stakeholders, by making ourselves available for discussions, including proactively organising presentations to different forums to explain the research project.

7 Dissemination

The outputs from this study will include a final report, a lay summary and an academic paper. These outputs will be available in downloadable format from the research projects designated website.

Working with our stakeholders (including the CASS review team) we will ensure the maximum distribution of these documents and make them available on various other professional and community website, with an interest in this area. Further, the project will generate peer reviewed publications in high ranking and relevant journals (such as Social Science and Medicine, Sociology of Health and Illness, British Medical Journal, Archives of Disease in Childhood, Journal of American Medical Association Pediatrics); articles in professional orientated and other relevant outlets (e.g., RCPCH, RCGP); presentations at academic conferences, professional meetings and community workshops. At the end of the project, we will organise a day conference, organised in partnership with key stakeholders, in which we launch and discuss the findings of the project.

8 Timeline

This timeline reflects the current situation in the NHS with COVID-19 and may need to be adjusted further. The current aim is to begin 1st January 2022.

Before formal start of project:	REC and HRA approval, appointment of posts, PPI and consultation with community and voluntary organisations, establish study steering committee
Months 1-7	Recruit children, young people and young adults and parents
Months 2-7	Data collection children, young people and young adults
Months 3-7	Preliminary Data Analysis – children, young people and parent interviews
Months 5-7	Recruit Care professionals
Months 8-16	Analysis and write-up
Months 12-16	Write final report, stakeholder workshops and dissemination

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