The Impact of Prenatal Screening on Women's Psychological Wellbeing

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B. Psychology (Honours)

Empirical thesis submitted in partial fulfilment of the requirements for the degree of

Master of Clinical Psychology

School of Psychology

University of Newcastle

October 2019

Declarations

Statement of Originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to this copy of my thesis, when deposited in the University Library*, being available for loan and photocopying subject to the copyright Act 1968.

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Acknowledgement of Collaboration

I hereby certify that the work embodied in this thesis has been done in collaboration with other researchers. I have included as part of this thesis a statement clearly outlining the extent of collaboration, with whom and under what auspices.

I contributed to the development of the research question, the database search, the statistical analysis, the interpretation of results and editing of the manuscript. Dr Linda Campbell contributed to the development of the research question, the formulation of the methodology, the interpretation of results, and editing of the manuscript. Dr Tracy Dudding-Byth contributed to the development of the research project and editing of the manuscript. Miss Paige Cornell assisted with ethics application and project development. Dr Rina Fyfe assisted in the data collection.

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Acknowledgements

Firstly, I would like to acknowledge my supervisor, Dr Linda Campbell. Thank you for your support and guidance over the past two years. Your input and encouragement has made this research project possible. I would also like to extend my thanks to Dr Rina Fyfe, who assisted with recruitment at the John Hunter Hospital, and Dr Tracy Dudding-Byth, who assisted with project design and review. Thank you to the women who took the time to participate in this study; without your input, this research project would not have been possible.

To my fellow Masters students, it has been great to spend the last two years learning with you. Thank you for the continued support and understanding, and making this journey a whole lot more achievable. A special mention to Paige for working on this project with me. Having someone to complete ethics applications with, and bounce ideas off, was invaluable.

Finally, thank you to my family, friends and partner for your extra support over the past two years. You have always believed that I could do this, even during the times when it felt impossible. I would not be where I am today without you.

Table of Contents

Declarations 2

Statement of Originality 2

Acknowledgement of Collaboration 2

Acknowledgements 3

Table of Contents 4

Manuscript Title Page 6

Abstract 7

Introduction 8

The Current Study 12

Method 13

Participants 13

Measures 13

Demographic Questions 13

Depression Anxiety Stress Scales-21 (DASS-21) 13

Decisional Conflict Scale (DCS) 14

Genetic Counseling Satisfaction Scale (GCSS) 14

Procedure 15

Design and Analysis 15

Results 16

Sample Characteristics 16

Characteristics of Women Who Received a High-Risk Result 17

Psychological Wellbeing of Participants Based on Type of Prenatal Test 19

Psychological Wellbeing of Participants Based on Type of Risk Result 20

The Relationship Between Decisional Conflict, Genetic Counseling Satisfaction and Psychological Wellbeing 21

Discussion 23

Strengths, Limitations and Directions for Future Research 26

Clinical Implications and Conclusions 28

Acknowledgement of Authorship 30

Human Studies and Informed Consent 30

Conflict of Interest 30

Animal Studies 30

References 31

Appendices 37

Appendix A: Journal Submission Requirements 35

Appendix B: Social Media Recruitment Blurbs 49

Appendix C: Standardized Questionnaires 51

Appendix D: Demographic Questions 54

Appendix E: Participant Information Statement 58

Appendix F: Participant Information Flyer 61

Appendix G: Consent Questions 62

Appendix H: Ethics Approval 63

Appendix I: Participation Flowchart 68

This thesis has been formatted as a manuscript to be submitted to the Journal of Genetic Counseling. See Appendix A for author guidelines. Please note that the tables and figures have been included in-text for purpose of thesis review and marking.

The Impact of Prenatal Screening on Women's Psychological Wellbeing

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Word Count: 6, 205

Abstract

Prenatal screening such as combined First Trimester Screening (cFTS) and Non-Invasive Prenatal Screening (NIPT) are designed to give women more information, choice and control in their pregnancies. However, more research is needed on how the process of prenatal screening can impact on women's psychological wellbeing. This study explored how screening results and associated factors, such as decisional conflict and satisfaction with genetic counseling, can impact on the psychological wellbeing of women. A total of 125 participants were recruited for the current study between April and July 2019, with women having undergone either cFTS or NIPT, or both. Participants were asked to complete an online survey with questionnaires about their prenatal screening experience and psychological wellbeing. It was found that women who received a high-risk prenatal screening result had significantly higher symptoms of depression, anxiety and stress, compared to women who received a low-risk result. It was also found that higher levels of decisional conflict related to the decision to undergo screening was associated with higher levels of depression, anxiety and stress symptoms. This research highlighted the importance of considering the impact of prenatal screening on psychological wellbeing, as poor mental health in pregnancy can lead to longer term negative outcomes for the developing fetus. Screening women for psychological symptoms throughout the process of prenatal screening, and recommending psychological intervention for women with prolonged elevation of symptoms or a high-risk screening result, may help to reduce the length and severity of psychological distress, and prevent ongoing mental health issues.

Key words: genetic testing, psychosocial, mental health, stigma, decision making

The Impact of Prenatal Screening on Women's Psychological Wellbeing

Pregnancy is currently at the forefront of legal, social and political debate in Australia, with a recent review of legislation on abortion and sex-selective termination (Flowers, 2019). One major factor that may influence a woman's decision about pregnancy is risk of fetal anomalies. Non-invasive prenatal screening provides women with early information about the risk of fetal anomalies, from approximately 10 weeks gestation (Royal Australian and New Zealand College of Obstetricians and Gynaecologists [RANZCOG], 2018). There are currently two screening tests available to Australian women in their first trimester of pregnancy, to detect an increased risk of Down syndrome and other genetic conditions associated with complex medical phenotypes: combined First Trimester Screening (cFTS) and Non-Invasive Prenatal Testing (NIPT). While these screening options provide women with more information, choice and control in their pregnancy, the outcomes of screening can result in dilemmas for women (and their partners) that can contribute to psychological distress (Lou, Mikkelsen, Hvidman, Petersen, & Nielsen, 2015; van Schendel et al., 2017). Despite rapidly changing technological advances, improved test sensitivity, and increased access and uptake, there is limited research investigating Australian women's experience of prenatal screening and the impact on mental health and wellbeing (Richmond et al., 2017).

cFTS and NIPT are screening tests which provide early indications of risk, but do not provide a definite diagnosis. These are often offered prior to invasive diagnostic tests (e.g., amniocentesis), which carry a small risk of miscarriage. cFTS is offered under a Partial Medicare Benefits Schedule to Australian women, with a cost of approximately AU$200 for the ultrasound component (Royal Australian College of General Practitioners [RACGP], 2019). cFTS generates an overall risk estimate categorised into high or low-risk, using information from ultrasound imaging of fetal nuchal translucency, maternal biomarkers and

maternal age (Bonacquisto, 2011; RANZCOG, 2018). Meanwhile, NIPT is a more recent technology involving analysis of cell-free DNA obtained from maternal plasma, to provide risk indications for trisomy 21, 18 and 13, as well as sex aneuploidies (Harraway, 2017). Although NIPT is readily available, it is not yet included under the Medicare system, costing AU$400-500 (Harraway, 2017). This occurs despite it being more accurate than cFTS, with a detection rate of 98% vs 85-90% for fetal aneuploidies; with a combined false positive rate of 0.13% (Gil, Accurti, Santacruz, Plana, & Nicolaides, 2017; Santorum, Wright, Syngelaki, Karagioti, & Nicolaides, 2017). While NIPT is more accurate than cFTS, particularly in detection of Down syndrome (trisomy 21), it's positive predictive value (ability to detect a condition that is actually present) is lower for less common aneuploidies, such as trisomy 18, trisomy 13 and sex aneuploidies, as well as microdeletion syndromes (RACGP, 2019; RANZCOG, 2018).

Given that NIPT is more accurate but more costly than cFTS, it has been suggested as a second tier screening tool after cFTS, or to women whose pregnancies are considered "high-risk" due to advanced maternal age (>35 years) or family history of fetal aneuploidies (Hui et al., 2015). However, RANZCOG (2018) recommend that all pregnant women are offered NIPT as an alternative to cFTS, although the fetal translucency ultrasound should still be undertaken. Importantly, prenatal screening only offer indications of risk, meaning a high-risk prenatal result should be followed-up by invasive testing, such as amniocentesis (Gil et al., 2017). While prenatal screening provides a way for pregnant women to receive information about fetal health without the risk of miscarriage, it is necessary to consider how this screening, and subsequent result and decision-making, can impact women's mental health and wellbeing. This is particularly important given that poor mental health during pregnancy is linked with an increased risk of adverse fetal, infant, and childhood outcomes (Dunkel Schetter & Tanner, 2012).

It has been found that women preparing to undergo a non-invasive ultrasound or an invasive prenatal test show higher anxiety compared to the general female population, although this appears transient dependent on the outcome, with women who receive low-risk results having a significant reduction in anxiety and stress (Kowalcek, Mühlhoff, Bachmann, & Gembruch, 2002; Nakić Radoš, Košec, & Gall, 2013). A systematic review of the effects of screening on pregnant women found anxiety levels were slightly above the typical range prior to screening, but normalised upon receiving a low-risk result (Lou et al., 2015). Similarly, anxiety rose significantly following a high-risk result, but normalised when diagnostic testing found no fetal aneuploidy (Lou et al., 2015). Similar results have been found for depressive symptoms, with high-risk results being associated with more symptoms of depression throughout pregnancy, continuing postnatally (Hippman, Oberlander, Honer, Misri, & Austin, 2009; Nevay, Hippman, Inglis, Albert, & Austin, 2016).

There has been some research specifically investigating anxiety and NIPT. Similar to other prenatal tests, anxiety levels are elevated at the time between receiving genetic counseling and undergoing NIPT (Lewis, Hill, & Chitty, 2016; van Schendel et al., 2016), with a significant reduction in anxiety following a low-risk result. As expected, anxiety levels remained high following a high-risk result (van Schendel et al., 2017). Residual anxiety has also been documented for some women with low-risk results, potentially due to a lack of confidence in NIPT, elevated baseline anxiety, and discrepancies between NIPT and previous prenatal screening results (Lewis et al., 2016). In Australia, Richmond et al. (2017) found women who previously received a high-risk cFTS result had significantly higher levels of anxiety at the time of NIPT, compared to women who received a low-risk cFTS result. Anxiety levels significantly reduced in all women one week after the results were received, with all women receiving a low-risk NIPT result. Richmond et al. noted they did not investigate factors contributing to anxiety reduction aside from a low-risk result. They

suggested it would be beneficial to consider the counseling women received, their health literacy, and importantly, to consider anxiety among those women who receive high-risk NIPT results.

There are a number of possible factors that may contribute to women's psychological wellbeing during the process of prenatal screening, aside from their result. One such factor is genetic counseling. Genetic counseling involves helping individuals understand and respond to the medical, familial and psychological implications of genetic contributors to disease, so they can make informed choices (Resta et al., 2006). Genetic counseling related to prenatal screening is often provided by a range of health professionals, such as general practitioners or obstetricians (RANZCOG, 2018). As such genetic counseling can be distinguished from the profession of being a genetic counselor, with genetic counselors receiving specific training in this area, as well as having many other roles, such research, teaching and policy making (Resta et al., 2006).

Whilst genetic counseling per se has not been found to reduce anxiety (Kaiser et al., 2002), a link has been found between anxiety and counseling satisfaction, with higher anxiety prior to counseling being associated with lower counseling satisfaction, with this anxiety remaining high after counseling (Tercyak, Johnson, Roberts, & Cruz, 2001). However, little is known about the impact of genetic counseling on wellbeing, with many studies including health professionals specifically trained for the purposes of the study, leaving counseling satisfaction unexplored (Lewis et al., 2016; van Schendel et al., 2017).

Although the link between genetic counseling and psychological wellbeing is unclear, research has suggested that greater satisfaction with genetic counseling is linked with lower decisional conflict (Hartwig, Miltoft, Malmgren, Tabor, & Jorgensen, 2019). Decisional conflict occurs when a decision involves risk or uncertainty of outcome, is emotionally laden, and involves challenges to personal values (Muller & Cameron, 2016; O'Connor, 1995). At

the time of prenatal screening, women who had a better understanding of the screening procedure and possible results, and therefore made an informed choice, had less decisional conflict and better psychological wellbeing (Dahl, Hvidman, Jørgensen, & Kesmodel, 2011; van Schendel et al., 2016).

While guidelines are provided on genetic counseling for prenatal screening in Australia (RANZCOG, 2018), pre and post-test counseling can be provided by a range of health care professionals, and may vary in quality. As such, it is important to consider how genetic counseling satisfaction and decisional conflict are related to psychological wellbeing; particularly as prenatal screening is voluntary, and should only be undertaken as an informed choice. That is, with sufficient knowledge, and in alignment with personal values (Marteau, Dormandy, & Michie, 2001).

The Current Study

To date, there have been several studies investigating the implementation of prenatal screening, and associated impact on psychological wellbeing (e.g., Lewis et al., 2016; Richmond et al., 2017; van Schendel et al., 2017). However, there is limited research investigating factors associated with prenatal screening that can impact on women's psychological wellbeing, particularly in an Australian context. While research does suggest a low-risk prenatal result reduces anxiety in pregnant women, it is unclear how decisional conflict, and genetic counseling satisfaction impact upon mental wellbeing.

The current study aims to address gaps in the literature by investigating the psychological wellbeing of women who have undergone prenatal screening in Australia, as well as their decisional conflict and counseling satisfaction. It was hypothesised that women who received a low-risk prenatal result would have lower levels of depression, anxiety and stress symptoms, compared to women who received a high-risk result. Secondly, it was

hypothesised that higher decisional conflict and lower genetic counseling satisfaction would be associated with higher levels of depression, anxiety and stress symptoms.

Method

Participants

A sample of 125 participants were recruited between April and July 2019. The participants were women who previously underwent cFTS and/or NIPT. Participants were over the age of 18, fluent in English, and underwent screening in Australia. Participants were recruited in multiple settings, including the Maternal Fetal Medicine unit at the John Hunter Hospital and from social media groups aimed at women in the perinatal period (see Appendix B for social media blurb). All women were provided with study information prior to providing consent. It was made clear to prospective participants that study participation would not affect their health care.

Measures

The current study was embedded within a larger survey, using a combination of standardized measures and demographic questions designed by the research team (see Appendices C and D). Only measures relevant to the current study will be outlined.

Demographic Questions. The study contained demographic questions, including participant age, education, income, and history of diagnosed mental health conditions. There were also questions relating to the participants' experience of prenatal screening, including the type of screen, time since screening, and their result.

Depression Anxiety Stress Scales-21 (DASS-21). The DASS-21 (Lovibond & Lovibond, 1995) is a 21-item self-report scale measuring emotion symptoms using three sub-scales: depression, anxiety and stress. Participants rate how much each item has applied to them over the previous week, using a 4-point scale ranging from 0 (*never*) to 3 (*almost always*). In the context of the current study, participants rated how much each statement

applied to them in the week after receiving their prenatal screening result. Higher scores indicated greater levels of distress, and are categorised from "normal" to "extremely severe". Scores for each sub-scale were doubled so they were comparable to norms from the DASS-42. The DASS-21 has acceptable reliability, with internal consistencies of .94, .87, and .91, for depression, anxiety, and stress respectively (Antony, Bieling, Cox, Enns, & Swinson, 1998). The DASS-21 has acceptable validity, distinguishing between clinical and non-clinical samples (Antony et al., 1998), and was established using a non-clinical sample (Crawford & Henry, 2003). The DASS-21 is an acceptable alternative to the Edinburgh Post Natal Depression Scale (EPDS; Miller, Pallant, & Negri, 2006), and has been used in studies involving pregnant women (Xavier et al., 2016), including pregnant women in Australia (Metcalf et al., 2017).

Decisional Conflict Scale (DCS). The DCS (O'Connor, 1995) is a 16-item self-report measure of decision making across five subscales: informed (knowledge about options, risks and benefits of screening), values clarity (knowing personal values about screening), level of support (assistance from others and absence of pressure), uncertainty (level of clarity about decision), and effective decision making (overall satisfaction with decision). Each item is scored from 0 (*strongly agree*) to 4 (*strongly disagree*), with the total score being recoded from 0 to100, for comparison to norms (Garvelink et al., 2019). Higher scores represent greater conflict. The DCS has acceptable reliability, with Cronbach's alpha ranging from .71 to .88, and construct validity (Garvelink et al., 2019; O'Connor, 1995).

Genetic Counseling Satisfaction Scale (GCSS). The GCSS (DeMarco et al., 2004; Tercyak et al., 2001) is a six-item self-report measure of personal satisfaction with the content and process of genetic counseling, with the definition of genetic counselling focusing on the provision of objective information. Each item is rated on a scale from 1 (*strongly disagree*) to 5 (*strongly agree*), with higher scores indicating greater satisfaction with

counseling. This measure has been validated in a population receiving prenatal genetic counseling (Tercyak et al., 2001), and has been shown to have acceptable reliability, with Cronbach's alpha ranging from .80 (Tercyak et al., 2001) to .90 (DeMarco et al., 2004).

Procedure

The survey study was delivered online via the Qualtrics (2019) platform. Prospective participants accessed the survey by following the link on the information pamphlet or social media advertisement. Participants were presented with the information statement and flyer (see Appendices E and F), outlining the purpose of the research and requirements for participation, followed by an initial question about consent to participate (see Appendix G). Participants then completed demographic questions and standardized measures. The survey took approximately 30 minutes to complete, was anonymous, and participants could exit at any time. This research was conducted with approval from the Hunter New England Human Research Ethics Committee (2019/ETH01243) and the University of Newcastle Human Research Ethics Committee (H-2019-0106; see Appendix H).

Design and Analysis

The current study used a cross-sectional survey design. The independent variable was type of prenatal screening result: high-risk or low-risk of fetal anomaly. The primary dependent variable was psychological wellbeing, measured using the DASS-21. Additional variables of interest included decisional conflict (measured using the DCS), and genetic counseling satisfaction (measured used the GCSS).

Statistical analyses were performed using SPSS version 26. Descriptive analyses and frequencies were run for demographic data and standardized measures. Non-parametric independent samples tests were used to compare DASS-21 scores based on type of result (high-risk or low-risk). Spearman's correlations were run between the DASS-21 sub-scales, showing moderate to strong correlations (r_s between .63 and .74), with these sub-scales being

combined into a total DASS-21 score for subsequent analyses. A series of Spearman's correlations were run to assess the relationships between the total DASS-21 score and other variables of interest. A multiple linear regression was then run to assess which variables were significant predictors of total DASS-21 score.

Results

Sample Characteristics

A total of 208 participants accessed the survey between April and July 2019. Fifteen (7.2%) were excluded as they had not completed prenatal screening, five (2.4%) were excluded as they were not offered any prenatal screening (it is unknown why screening was not offered), seven (3.4%) were excluded as they underwent a prenatal screen other than cFTS or NIPT, and 56 (26.9%) were excluded as they were missing key data relating to the outcome variables, such as the result of their screening and/or their DASS-21 scores (see Appendix I for participation flowchart). Hence, the final sample included 125 participants. This sample size was considered sufficient as other studies in the area of prenatal testing have been published with smaller sample sizes, with Nakic et al., (2013) having a sample size of 76. There were no significant differences between included and excluded participants in regards to age ($t = 1.42$, $df = 201$, $p = .163$), education level ($\chi2(4) = 1.67$, $p = .792$) or presence of a mental health condition ($\chi2(1) = 0.15$, $p = .703$). There was a significant difference in regard to household income, with people of higher earnings being more likely to complete the survey ($\chi2(4) = 12.25$, $p = .016$).

Characteristics of participants are presented in Table 1. Women's mean age was 32.6 years (range 19 - 37). Most women were university educated (70.4%), had a yearly household income above $80, 000 (86.4%), and had planned their pregnancy (84.8%). Of the women who participated, 15 (12%) were diagnosed with a mental health condition, including anxiety, depression, post-traumatic stress disorder, and bipolar disorder (type 2). Of those who

participated, 48 (38.4%) had cFTS only, 26 (20.8%) had NIPT only, and 51 (40.8%) had both. Twenty-five participants (20%) did not know the difference between cFTS and NIPT prior to entering the survey.

Table 1

Demographic Information of Participants, N = 125

Characteristic	n (%)
Age (Years)	
M(SD)	32.63 (5.69)
Education	
High school	16 (12.8)
Diploma	21 (16.8)
University (bachelor degree)	52 (41.6)
University (post graduate degree)	36 (28.8)
Yearly household income	
$0-$18,200	2 (1.6)
$18,201-$37,000	5 (4)
$37,001-$80,000	10 (8.0)
$80,001-$180,000	83 (66.4)
$180,001 and over	25 (20.0)
Diagnosed mental health	
Yes	15 (12)
No	110 (88)
Planned pregnancy	
Yes	106 (84.8)
No	19 (15.2)
Type of prenatal screening	
Combined First Trimester Screen only	48 (38.4)
Non-Invasive Prenatal Testing only	26 (20.8)
CFTS and NIPT	51 (40.8)
Time since test result received	
Less than 1 month	13 (10.4)
1 - 3 months	15 (12)
3 - 6 months	27 (21.6)
6 - 12 months	29 (23.2)
Over 12 months	41 (32.8)

Characteristics of Women Who Received a High-Risk Result

Seven women (5.6%) in the study received a high-risk cFTS result, and did not have NIPT. These women all had follow-up testing, with five having invasive testing (e.g.,

amniocentesis), and two not specifying what follow-up testing they had. Three of these women (42.9%) had their high-risk cFTS result delivered over the phone, and four (57.1%) had the information delivered face-to-face, with two women (28.6%) receiving additional written information. Four women (57.1%) had the result delivered by their GP, and three (42.9%) by another health professional (nurse, obstetrician, and fetal medicine specialist). Of these women, six (85.7%) reported they would make the same choice about testing in the future, and one reported they would not undergo prenatal screening in the future, providing the reason that it was "too stressful".

Seventeen women (13.6%) received a high-risk result from their NIPT. Nine of these women (52.9%) had their results delivered over the phone, and one had their result delivered via email due to being overseas. Seven women (41.2%) had their results delivered face-to-face, with five (29.4%) also being offered written information. Eight of these women (47.1%) had the result delivered by an obstetrician, five (29.4%) by a GP, two (11.8%) by a genetic counsellor, one by a midwife, and one by a fertility specialist. Of the women who received a high-risk NIPT result, 12 (70.6%) received a high-risk result for Down Syndrome, and five (29.4%) received a high-risk result for another condition (Turner Syndrome, Triple X Syndrome, Klinefelter Syndrome, Trisomy 8, and increased reading for chromosome 20). Ten of these women (58.8%) were offered genetic counseling following their high-risk result, with most counseling being provided by genetic counsellors (70%). Only two women (11.8%) engaged in psychology or counseling support following their high-risk result, and only one health professional recommended this support as an option. It is unclear whether women who did not engage were offered psychological or counseling support.

Twelve women who received a high-risk NIPT result underwent follow-up testing, with five (29.4%) having ultrasound testing, and seven (41.2%) having invasive diagnostic testing (e.g., amniocentesis). Five women (29.4%) chose not to have any further follow-up

testing, although reasons for this were not explored. Of the women who did have follow-up testing, eight (66.7%) had their high-risk result confirmed. Of the women who had follow-up testing, nine (75%) chose to continue with their pregnancy, two (16.7%) decided to terminate their pregnancy, and one woman was still deciding whether to continue or terminate their pregnancy. For the women who had decided about their pregnancy, eight (64.7%) did this in the second trimester (13-26 weeks). Thirteen women (76.5%) reported they would make the same choice to undergo NIPT in the future, and four (23.5%) reported they would choose not to undergo NIPT in the future, but did not provide a reason for this.

Psychological Wellbeing of Participants Based on Type of Prenatal Test

All participants completed the DASS-21, with participants answering retrospectively about the week after receiving their prenatal screening result. Mean scores for depression (M = 3.26, SD = 7.22, range 0 - 40), anxiety (M = 2.38 SD = 5.65, range 0 - 40), stress (M = 5.70, SD = 8.5 range 0 - 42) and total score (M = 11.34, SD = 20.35) were all within one standard deviation of the norms. Data was positively skewed, which is expected for clinical measures such as the DASS-21, with most women scoring within the normal ranges for depression (n = 111, 88.8%), anxiety (n = 112, 89.6%) and stress (n = 110, 88%). Due to the non-normal distribution of DASS-21 data, non-parametric tests were conducted.

A Kruskal-Wallis Test was conducted to assess the differences between DASS-21 scores for women who underwent cFTS only, for women who underwent NIPT only, and for women who underwent both cFTS and NIPT. No significant differences were found between these groups in regard to symptoms of depression ($\chi^2(2) = 0.55$, $p = .759$), anxiety ($\chi^2(2) = 0.49$, $p = .782$), or stress $\chi^2(2) = 0.15$, $p = .928$). As there was no difference between these groups, they were not separated for the following analyses.

Psychological Wellbeing of Participants Based on Type of Risk Result

A Mann-Whitney U Test was conducted to compare DASS-21 scores between women who received high-risk prenatal screening results (n = 24), and women who received low-risk prenatal screening results (n = 101; see Figure 1). Women who received a high-risk result had significantly higher scores for symptoms of depression (M = 12.58, SD = 11.53 vs. M = 1.05, SD = 2.88; $p < .001$), anxiety (M = 7.50, SD = 9.40 vs M = 1.17, SD = 3.39; $p < .001$) and stress (M = 14.92, SD = 12.96; M = 3.51, SD = 5.24; $p < .001$) compared to women who received a low-risk result. These differences remained after controlling for pre-existing mental health diagnoses ($p < .001$).

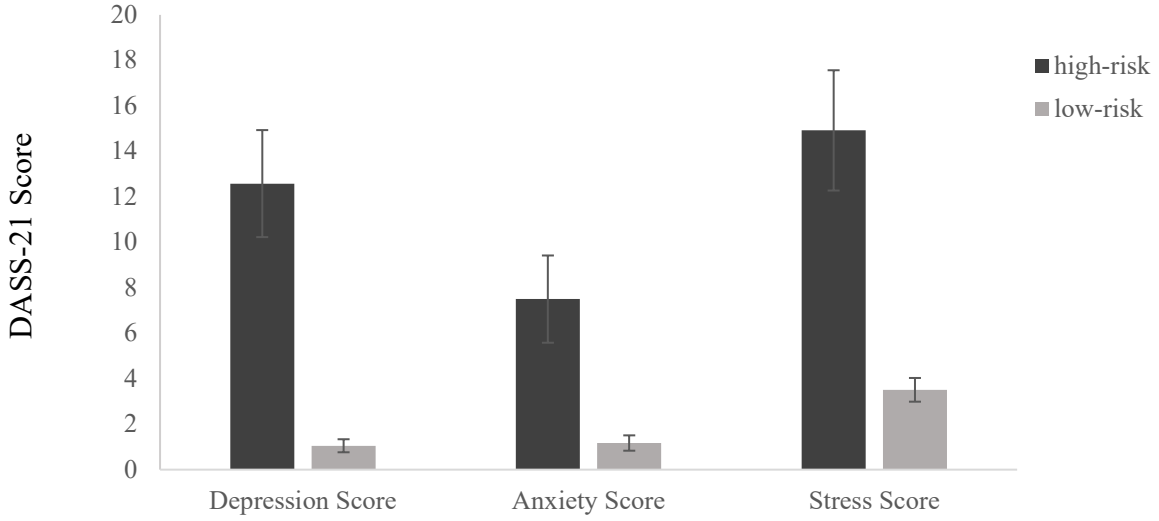
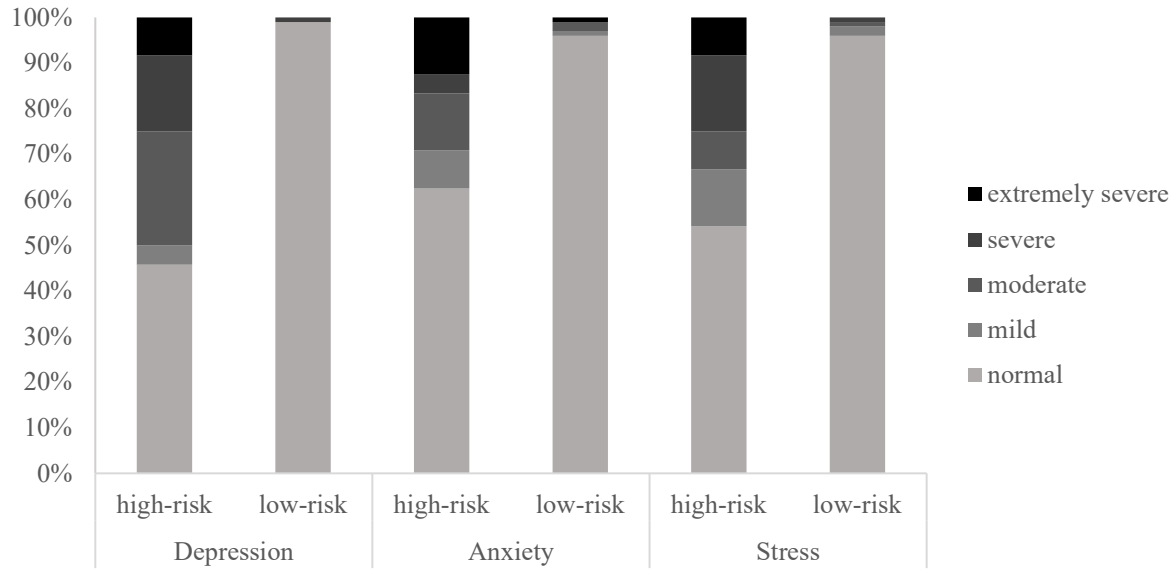


Figure 1. Comparison of Depression Anxiety Stress Scale-21 scores between women who received high-risk and low-risk prenatal screening results. Error bars represent standard error.

For the women who received high-risk results, six (25%) fell within the moderate range for their depression symptoms scores, four (16.7%) within the severe range, and two (8.3%) within the extremely severe range. In regard to anxiety scores, three (12.5%) fell within the moderate range, one (4%) within the severe range, and three (12.5%) within the extremely severe range. For stress symptoms, two (8.3%) fell within the moderate range, four (16.7%) within the severe range, and two (8.3%) within the extremely severe range.

In comparison, for the women who received low-risk results, one (1%) fell within the severe range for depressive symptoms, while the remainder were within normal ranges. In regards to anxiety symptoms, two (2%) fell within the moderate range, and one (1%) within the extreme range. For stress symptoms, one (1%) fell within the moderate range, and one (1%) within the severe range. These findings are summarised in Figure 2.



F*igure 2.* Comparison of Depression Anxiety Stress Scale-21 depression, anxiety and stress categories between women who received high-risk and low-risk prenatal screening results.

The Relationship Between Decisional Conflict, Genetic Counseling Satisfaction and Psychological Wellbeing

Due to strong correlations between the DASS-21 sub-scales (depression, anxiety and stress), the total score was used for this analysis. Aside from the type of risk result, DCS scores, whether genetic counseling was provided, and GCSS scores were included in analysis. Higher scores on the DCS (n = 124, *M* = 11.41, *SD* = 10.54, range = 0 – 76.76) represent higher levels of conflict about decision making, and higher scores on the GCSS (n = 108, *M* = 23.06, *SD* = 6.00, range = 6 – 30) indicate greater satisfaction with genetic counseling. Fifteen women (12%) reported they did not receive genetic counseling.

Due to the non-normal distribution of data, Spearman's correlations were run to assess the relationship between total DASS-21 score, demographic variables, DCS, and

GCSS (see Table 2). As anticipated, there was a significant correlation between type of risk result and total DASS-21 score ($r_s(125) = -.46$, $p < .001$). A small, significant correlation was also found between decision conflict score and total DASS-21 score ($r_s(124) = .21$, $p = .019$). No significant correlations were found between total DASS-21 score, genetic counseling satisfaction or any of the demographic variables (age, household income, education, diagnosis of a mental health condition, whether or not the pregnancy was planned, the type of prenatal screening, and the time since prenatal screening).

Table 2

Correlations Between Total Depression Anxiety Stress Scale-21 Score and Other Variables of Interest

	Total DASS-21 score
Type of risk result (high/low risk)	-.46**
Decisional Conflict Scale	.21*
Whether genetic counseling was provided	-.09
Genetic Counseling Satisfaction Scale	-.04
Age	.17
Yearly household income	-.03
Education	.05
Diagnosis of a mental illness	-.10
Planned pregnancy	.04
Type of prenatal screen	-.02
Time since prenatal screen	.02

Note. *$p < .05$, **$p < .01$

A hierarchical multiple linear regression was used to assess the ability of type of risk result (high or low-risk) and decisional conflict score to predict total DASS-21 score (models summarised in Table 3). These predictor variables were included as they were significantly correlated with total DASS-21 score. Preliminary analyses were run to check assumptions, with all assumptions being met. Type of risk result was added in step 1, as it had the largest correlation with total DASS-21 score. This model explained 32% of variance in total DASS-21 score (Adjusted $R^2 = .320$), $F(1, 122) = 59.91$, $p < .001$. Decisional conflict scores were added in step 2, with the total variance explained by this model being 37.2% (Adjusted $R^2 =$

.372), F(2, 121) = 37.35, p <.001. Decisional conflict scores explained an additional 5.6% of variance (R^2 change =.056) in total DASS-21 scores, after controlling for type of risk result, F change (1, 121) = 10.98, p < .001. In this final model, type of risk result was the largest predictor of variance in total DASS-21 score (β = -.55, p < .001). Decisional conflict was also a significant predictor of total DASS-21 scores (β = .24 p = .001).

Table 3

Summary of Regression Models

	R-squared	Adjusted R-squared	R-squared change	F change	*p*
Model 1 (type of risk result)	.35	.32	.326	58.91	< .001
Model 1 (type of risk result and decision conflict score)	.38	.37	.056	10.98	.001

Discussion

The current study aimed to investigate the impact of prenatal screening results and associated factors on women's psychological wellbeing in Australia. Consistent with our hypothesis, significantly higher levels of depression, anxiety and stress symptoms were found in women who received high-risk results, compared to women who received low-risk results. There was no significant difference in these symptoms based on the type of screening women underwent. As hypothesised, more decisional conflict was associated with higher levels of depression, anxiety and stress symptoms. However, contrary to our hypothesis, genetic counseling satisfaction was unrelated to depression, anxiety and stress symptoms.

Previous research suggests women experience elevated anxiety prior to prenatal screening (Lou et al., 2015; Nakić Radoš et al., 2013; van Schendel et al., 2016). The current study extends upon this, by showing higher levels of depression, anxiety and stress symptoms in women who receive high-risk results. We found almost one third of women with high-risk results fell in the clinical range for anxiety symptoms, and almost half fell in the clinical

range for stress symptoms, compared to less than 5% of women with low-risk results. This is consistent with previous research, where anxiety and stress levels significantly lowered in women who received low-risk results, but increased in women who received high-risk results (Kowalcek et al., 2002; Lewis et al., 2016; Richmond et al., 2017; van Schendel et al., 2017).

We also found higher levels of depressive symptoms in women with high-risk results, where more than half fell in the clinical range for depressive symptoms, compared with 1% of women who received low-risk results. This was consistent with previous research on cFTS, which has shown elevated levels of depressive symptoms in women who received high-risk cFTS results (Hippman et al., 2009), which continue through pregnancy and post-natally. (Nevay et al., 2016). The findings of the current study and consistency with previous research is noteworthy, as there is a large body of literature indicating that poor psychological wellbeing during pregnancy can have lasting negative effects on the developing fetus (Dunkel Schetter & Tanner, 2012). Moreover, research has shown strong links between prenatal and postnatal anxiety and depression; with depression, anxiety and stressful events in pregnancy being the strongest predictors of postnatal depression (Robertson, Grace, Wallington, & Stewart, 2004).

Interestingly, the current study showed that symptoms of depression, anxiety and stress were significantly higher in women who received high-risk results, even after accounting for pre-existing mental health diagnoses. Despite this, there seems to be a lack of focus on mental health support for women who received high-risk results, with only two engaging in psychological support. It is unclear whether this was due to women's decision not to engage, or whether psychological support was not offered by health care professionals.

Contrary to our hypothesis, satisfaction with genetic counseling was unrelated to psychological wellbeing. This was consistent with the research of Kaiser et al. (2002), who found satisfaction with genetic counseling was not associated with anxiety levels following

counseling. However, our research was inconsistent with Tercyak et al. (2001), who found higher anxiety in women who had lower satisfaction with genetic counseling. Although, this study showed higher anxiety and lower counseling satisfaction occurred in women who had higher levels of anxiety prior to counseling, suggesting that baseline anxiety may be predictive of later anxiety, rather than counseling satisfaction. Given counseling satisfaction is a subjective measure, it is possible women's satisfaction with counseling is not reflective of their objective knowledge, and it may be that objective knowledge is more predictive of psychological wellbeing than perceived satisfaction with counseling. Additionally, participants in the Tercyak et al. study received genetic counseling from board approved genetic counselors, whereas participants in the current study received post-test counseling from a range of health professionals (e.g., GPs and obstetricians), with the provider of pre-test counseling not being assessed. Moreover, the definition of genetic counseling provided to participants of the current study focused on the provision of objective information, and did not encompass the psychosocial care that can be involved in genetic counseling. These factors may explain why we did not find a relationship between counseling satisfaction and psychological wellbeing.

Interestingly, we did find that higher decisional conflict was associated with poorer psychological wellbeing, with past research showing a link between lower counseling satisfaction and higher decisional conflict (Hartwig et al., 2019). This suggests further investigation between these factors may be warranted. The finding that higher decisional conflict was associated with higher levels of psychological distress also extends upon other previous findings. Past research has shown higher decisional conflict was associated with lower knowledge of prenatal testing and less informed decision making, with less informed decision making being associated with poorer psychological wellbeing (Dahl et al., 2011; van Schendel et al., 2016). To our knowledge this is the first study showing a direct link between

decisional conflict and psychological distress in the context of prenatal screening, which remained even after accounting for the type of risk result (high or low-risk). This suggests that addressing decisional conflict when offering prenatal screening may help to mitigate some of the psychological distress experienced by women.

Strengths, Limitations and Directions for Future Research

A key strength of this study is the insight it provides into the impact of prenatal screening on the psychological wellbeing of women within the Australian context. To our knowledge, only one other study to date has considered the impact of cFTS and NIPT on psychological wellbeing in Australia; however, this study focused on anxiety symptoms, and did not include women who received high-risk NIPT results (Richmond et al., 2017). Our study was the first to consider depressive, anxiety and stress symptoms within the context of both high-risk and low-risk prenatal screening results. Another strength was consideration of factors that may influence mental health, aside from the screening result itself. This has not been a large focus of previous studies, particularly within Australia.

While this study displays several strengths, there are also some limitations worth noting. We had a small sample-size of women who received high-risk results, and no power calculation was completed to determine the necessary sample size for this study. There have been other studies on prenatal screening with smaller overall sample sizes (e.g., Nakic et al., 2013), but these did not specifically consider women with high-risk results. This should be considered when interpreting the results. Participants were also predominantly university educated and had a high income, potentially reducing the generalisability of the results. However, given that NIPT is not Medicare funded, this sample may indeed be representative of the women accessing prenatal screening. Informed choice and knowledge of screening were not assessed in the current study, as measures of informed choice are not directly comparable for NIPT and cFTS. Past literature has indicated informed choice is an important

aspect of prenatal screening, and may be linked to decisional conflict and psychological wellbeing (van Schendel et al., 2016). By not including this measure, we could be missing a predictor of mental wellbeing. Measures of informed choice could be included in future studies that investigate prenatal screening. It is also worthwhile noting that the EPDS was not included as a measure in the current study. While the DASS-21 is considered an acceptable alternative to the EPDS, the EPDS remains the gold standard for screening for pre and post-natal depression (National Institute for Health and Care Excellence, 2015). As such, future studies should consider included this measure.

Another limitation was the cross-sectional and retrospective nature of the current study. As such, we were unable to assess how psychological wellbeing changed over time, or baseline levels at the time of screening. Assessing mental health over time would be useful, given prenatal screening and testing procedures can occur over several weeks. It would also be important to monitor psychological wellbeing in women who chose to terminate their pregnancy, as well as those continuing with pregnancy. Future studies could utilise a longitudinal design to better monitor psychological wellbeing over time. Qualitative research involving women with high-risk results could also provide richer information about their experience of psychological wellbeing in context of pregnancy and prenatal screening.

A final limitation was the measurement of genetic counseling. The GCSS was designed to assess counseling provided by genetic counselors, which encompasses the provision of objective information as well as psychosocial care. In contrast, genetic counseling provided to women in the current study was likely from a range of health professionals, with this not being specifically assessed, and the definition of genetic counseling provided to participants focused on the provision of objective information. Moreover, our analysis of genetic counseling satisfaction did not consider who provided the counseling. It is possible that there were differing levels of satisfaction based on the type of

professional who provided the counseling. As such, our measurement of genetic counseling satisfaction may not have accurately captured women's experiences. Future research could address this by using a more resent measure of patient reported outcomes of counseling, such as the Genetic Counselling Outcome Scale (McAllister, Wood, Dunn, Shiloh, & Todd, 2011), as well as accounting for the type of health professional who provided counseling.

Clinical Implications and Conclusions

The current research highlights the importance of considering psychological wellbeing within the context of prenatal screening. For many women, prenatal screening can be seen as a standard aspect of care in pregnancy. However, guidelines maintain prenatal screening is an option that women should undertake voluntarily when they have sufficient understanding of the procedure (RANZCOG, 2018). This screening can place women in an ethical dilemma they may not be prepared for, where they must decide to continue or terminate their pregnancy based on risk information given early in pregnancy. Choosing a termination, or continuing a pregnancy where a child will be born with a genetic condition, are both choices associated with stigma and ongoing consequences, particularly in the current Australian climate, where discord on abortion laws is ongoing.

It is therefore necessary for genetic counseling to include information about the psychological distress and ethical dilemmas that can be caused by undergoing prenatal screening. Given that women in Australia receive genetic counseling from a wide range of health professionals, it is essential that these professionals are aware of the broader role of psychosocial support in genetic counseling. This is important given the large body of literature on the negative impacts of poor psychological wellbeing in pregnancy (Dunkel Schetter & Tanner, 2012). It would be beneficial for women to be routinely screened for symptoms of depression, anxiety and stress while in the process of prenatal screening. If women presented with persistently elevated symptoms, it would be useful to refer them for

psychological intervention and support, as this may help ameliorate psychological distress. It is particularly important that women who receive a high-risk result which is confirmed via invasive testing receive ongoing psychological support. This would assist women who choose to continue with their pregnancy in preparing for the inevitable changes associated with having a child with a disability and complex medical needs (Lindblad, Rasmussen, & Sandman, 2005).

Our research also highlights the contribution of decisional conflict to psychological wellbeing. While there is no way to negate the prenatal result that a woman receives, strategies designed to reduce decisional conflict may help to mitigate some symptoms of depression, anxiety and stress. Research suggests use of decision aids designed to increase personal participation in health care decisions can reduce decisional conflict (Garvelink et al., 2019). In fact, there is now a decision aid booklet available for women in Australia, which covers both cFTS and NIPT (Murdoch Childrens Research Institute, 2018). As such, it may be beneficial for health professionals to implement decisional aids when providing women with information about prenatal screening.

Overall, prenatal screening is designed to give women more information, choice and control within their pregnancy. However, this study highlights the need to consider ethical dilemmas associated with screening, and the possible implications on mental health and wellbeing of women. Women have the right to choose prenatal testing, but they also deserve to be informed about the potential implications of this, aside from increased risk of a fetal anomaly. Indeed, some of the most serious implications of screening may be the ethical dilemmas, stigma and psychological distress upon receiving a high-risk result. While there is no simple way to mitigate this psychological distress, the use of decision aids, monitoring wellbeing and provision of psychological intervention where necessary may help to improve women's wellbeing following their prenatal screening result.

Acknowledgement of Authorship

I hereby certify that the work embodied in this thesis contains scholarly work of which I am a joint author. This is a written statement, endorsed by my supervisor, and attesting to my contribution to the joint scholarly work.

Human Studies and Informed Consent

All procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and standards, laid down in the 1964 Helsinki Declaration. Ethical approval of the study was granted by the Hunter New England Human Research Ethics Committee (2019/ETH01243) and the University of Newcastle Human Research Ethics Committee (H-2019-0106; see Appendix H). Informed consent was obtained from all individual participants included in the study.

Conflict of Interest

All authors declare they have no conflict of interest.

Animal Studies

No non-human animal studies were carried out by the authors for this article.

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Appendix A: Journal Submission Requirements

Journal of Genetic Counseling

National Society of Genetic Counselors

AUTHOR GUIDELINES

SECTIONS

1. Aims and Scope
2. Submission
3. Manuscript Categories and Requirements
4. Preparing the Submission
5. Editorial Policies and Ethical Considerations
6. Author Licensing
7. Publication Process After Acceptance
8. Post-Publication
9. Wiley Author Resources
10. Editorial Office Contact Details

1. AIMS AND SCOPE

The **Journal of Genetic Counseling (JOGC)**, published for the National Society of Genetic Counselors, is a timely, international forum addressing all aspects of the discipline and practice of genetic counseling. The journal focuses on the critical questions and problems that arise at the interface between rapidly advancing technological developments and the concerns of individuals and communities at genetic risk. The publication provides genetic counselors, other clinicians and health educators, laboratory geneticists, bioethicists, legal scholars, social scientists, and other researchers with a premier resource on genetic counseling topics in national, international, and cross-national contexts.

As a crucial resource for genetic counselors and associated professionals, the Journal's primary purpose is to report original research in the following areas:

- **Genetic Counseling Theory, Methods, and Practice**: addresses genetic counseling in clinical or non-clinical settings;
- **Public Health, Public Policy, and Access and Genetics Service Delivery**: addresses public health genomics, health behaviors, legal or policy aspects related to genetic counseling and genetic testing, precision medicine, health disparities, models of genetics services delivery;
- **Education and Genetics Professional Workforce Issues**: addresses educational training, professional development, and workforce topics related to genetic counseling;
- **Ethical, Legal, Psychological, and Social Issues**: addresses ethical, legal, psychological, and/or social issues related to genetic counseling, genetic services, and/or genetic information regarding

individuals, communities, and the public
- **Risk Assessment**: addresses algorithms, theoretical models, or empirical data for use in genetic counseling risk assessment.

In addition to research articles, regular features of the Journal of Genetic Counseling include case presentations, editorials, rapid publications, and letters to the editor. Note: The Journal does not publish non-human animal studies.

Return to Guideline Sections

2. SUBMISSION

Once the submission materials have been prepared in accordance with the Author Guidelines, manuscripts should be submitted via the Journal's Editorial Manager site: https://www.editorialmanager.com/jogc/default.aspx. More details on how to use Editorial Manager are also available at https://www.editorialmanager.com/jogc/default.aspx.

A manuscript is considered for review and possible publication on the condition that it is submitted solely to the journal, and that the manuscript or a substantial portion of it is not under consideration elsewhere. Presentation of the content at meetings prior to submission is acceptable. However, authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium. Note, this journal uses iThenticate's CrossCheck software to detect instances of overlapping and similar text in submitted manuscripts.

The submission system will prompt the author to use an ORCiD ID (a unique author identifier) to help distinguish their work from that of other researchers. Click here to find out more.

For help with submissions, please contact the Editorial Office at JOGC@Wiley.com. When necessary, the Editorial Office staff may refer questions to the Editor-in-Chief.

Return to Guideline Sections

3. MANUSCRIPT CATEGORIES AND GENERAL REQUIREMENTS

MANUSCRIPT CATEGORIES

Original Articles. The Journal of Genetic Counseling seeks papers reporting exciting, timely, original research in the discipline and practice of genetic counseling. The Journal considers papers using a form of systematic study or inquiry to address a question to be original research. Systematic study can be approached using a variety of methods, such as empirical methods, systematic literature review methods, normative or conceptual research methods. Original articles:

- include an abstract and key words;
- are no more than 25 double-spaced pages in length for quantitative studies and no more than 35 double-spaced pages in length for qualitative or non-empirical studies (excluding Supplemental Information);
- have no more than 5 display items (tables + figures), and any additional display items will need to be submitted as Supplemental Information. Large tables should always be published as online only material;
- report relevant information per appropriate methodologic guideline (see Research Reporting Guidelines below).

Case Studies. Case studies are a valuable tool in the presentation of genetic counseling practice. They can serve to demonstrate a counseling model or to stimulate thought about a difficult ethical or counseling situation the author has encountered. In a case study, the paper is focused on the case(s) presented with the intention of alerting the reader to broader issues relevant to practice for the readers'

consideration. Note: the Journal of Genetic Counseling does not publish case studies whose sole purpose is to report clinical and molecular information. Case Studies should be concise and focused. They should address observations of patient encounters (usually 1-3) or a single small family that add substantially to the practice and discipline of genetic counseling. Case Studies:

- include an abstract and key words;
- are no more than 15 double spaced pages in length (excluding Supplemental Information);
- have no more than 2 display items (tables + figures), and any additional display items will need to be submitted as Supplemental Information. Large tables should always be published as online only material.

Professional Issues. These article types feature pieces that communicate reflections by the author on the discipline and practice of genetic counseling. Professional Issues:

- include an abstract and key words;
- are no more than 25 double-spaced pages in length (excluding Supplemental Information);
- have no more than 2 display items (tables + figures). and any additional display items will need to be submitted as Supplemental Information. Large tables should always be published as online only material.

Invited Commentary. This type of paper is generally solicited from the Editor but is a submission welcomed from all contributors. It should have a title page and be accompanied by a list of key words for indexing purposes. Commentaries/Editorials often address matters of interest or controversy to the readership.

Brief Reports. These are very brief reports offered in a letter format reporting an observation that adds to the knowledge of the discipline and practice of genetic counseling. They are no more than 9 double spaced manuscript pages in length (excluding Supplemental Information). The manuscripts are not subdivided into sections nor do they include an abstract. Key words are required for indexing purposes.

Correspondence. These are letters to the editor and generally comment on previously published work in the Journal of Genetic Counseling. These are kept brief and to the point; they do not include an abstract, key words, tables, or figures. Like all other material published in the Journal of Genetic Counseling, correspondence is subject to editorial or peer review. The corresponding author of the original manuscript which is the subject of the submitted letter will be offered the opportunity to respond. If a response is provided, every effort will be made to publish these letters together. Only one round of comment is allowed.

Rapid Communications. The Journal of Genetic Counseling features a new section devoted to the rapid communication of full-length, critically reviewed papers reporting new and important advances that are highly likely to have an immediate and critical impact on the discipline and practice of genetic counseling. Our goal is that these manuscripts will be published online approx. 4 weeks after acceptance. In order to have a manuscript considered for Rapid Communication, authors must send a letter of intent along with an abstract to the Editor for consideration prior to submission. The letter of intent should outline the author's rationale for publishing the article as a rapid publication. The Editor or Deputy Editor will respond to the author with a decision. Manuscripts accepted for Rapid publication must adhere to the format of an original research article in the Journal of Genetic Counseling.

Practice Guidelines. These article types address specific areas of genetic counseling and are submitted by the National Society of Genetic Counselors' Practice Guidelines Committee.

Review Articles. The Journal of Genetic Counseling publishes occasional topical reviews. Authors should contact the Editor-in-Chief prior to submission. Note: submissions that describe a systematic process for reviewing the literature to address a research question (e.g., systematic reviews, scoping reviews) are considered original research and are included in the Original Article category.

Book Reviews. Authors may contact the Editor-in-Chief with a proposal to submit a book review. The topic of the reviewed book should be closely aligned with the mission of the Journal. If the proposal is

approved for the submission, instruction will be provided by the editor.

Conference Reports. The Journal of Genetic Counseling occasionally publishes an executive summary of an important conference or scientific meeting that involves topics related to the scope of the Journal. The Journal also on occasion publishes the abstracts of an important meeting on a selected basis. Authors should contact the Editor-in-Chief prior to submission.

Corrigenda and Errata. These manuscripts are brief communications to correct errors in previously published work in the Journal of Genetic Counseling. The former is for errors that were responsibility of the author(s), and the latter are for errors that are responsibility of the Journal, including editorial staff and production. These may be written by the corresponding author of the relevant manuscript or they may be composed by an editor.

GENERAL REQUIREMENTS

Format

Manuscripts should be double-spaced with 1 inch margins and 12 point font.

English Language

Manuscripts must be submitted in grammatically correct American English. Manuscripts that do not meet this standard cannot be reviewed. Authors for whom English is a second language may wish to consult an English-speaking colleague or consider having their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found at https://wileyeditingservices.com/en/. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

Revisions

Please submit a marked version (tracked, highlighted, etc) and unmarked version of revised manuscripts.

Ethical Compliance

For all research involving human participants, please include a statement in the Methods section confirming that your study was reviewed by an institutional review board/human investigations committee/ethics committee (include name of committee) and approved or waived as human subjects research.

The Journal of Genetic Counseling does not publish research involving non-human animals.

Informed Consent

The Journal requires that all appropriate steps be taken in obtaining informed consent of all human subjects participating in the research comprising the manuscript submitted for review and possible publication, and statements to this effect must be included under the subheadings, "Human Studies and Informed Consent". For all manuscript categories, identifying information should not be included in the manuscript unless the information is essential for scientific purposes and the study participants or patients (or parents or guardians) give written informed consent for publication. The editors reserve the right to reject manuscripts that do not comply with these requirements. The author will be held responsible for false statements or failure to fulfill these requirements.

Conflict of Interest Statement

The Journal requires that all authors disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise, that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or directly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include, but are not limited to, patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. The existence of a conflict of interest does not preclude publication in this journal.

If the authors have no conflict of interest to declare, they must also state this in the manuscript. It is the responsibility of the corresponding author to review this policy with all authors and collectively to list in

the manuscript under the subheading "Conflict of Interest" ALL pertinent commercial and other relationships.

The above policies are in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals produced by the International Committee of Medical Journal Editors (http://www.icmje.org/).

Return to Guideline Sections

4. PREPARING THE SUBMISSION

Parts of the Manuscript

The manuscript should be submitted in separate files: cover letter; main text file; tables; figures; supplementary information files.

Cover Letter

The cover letter should include a statement that the work presented in the manuscript has not been published elsewhere and is not currently under review elsewhere.

If the study includes original data, at least one author must confirm in the cover letter that he or she had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Main Text File

The main text file should be presented in the following order (as appropriate for article type):

1. Title Page
2. Abstract and keywords
3. Main text
4. Author Contributions
5. Acknowledgements
6. Conflict of Interest
7. Human Studies and Informed Consent
8. Animal Studies
9. References
10. Figure legends

Tables, figures and supplementary information files should be supplied as separate files. Figures must be clearly labeled.

Title Page

The title page should include (in this order) the title of the article, authors' names (no degrees), authors' institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted, and suggested running head. The affiliation should comprise the department, institution (usually university or company), city, and state (or nation) and should be typed as a numbered footnote to the author's name. The suggested running head should be less than 80 characters (including spaces) and should comprise the article title or an abbreviated version thereof. The title page should also include the telephone number and e-mail address of the one author designated to review proofs.

Please denote cases of equal authorship with a footnote: In the case of joint first authorship, a footnote should be added to the author listing, e.g. 'X and Y should be considered joint first author' or 'X and Y should be considered joint senior author.

Authors may benefit from referring to Wiley's best practice tips on Writing for Search Engine Optimization.

Abstract

Please provide an unstructured abstract of no more than 300 words containing the major keywords summarizing the article. The abstract should include a description of the study's objective, methods or methodological approach, sample, measures or main outcome variables, main results, and conclusion.

Keywords

Please provide three to six keywords to be used for indexing the article. Please refer to this list.

Main Body

For Original Research articles, all major sections should carry section headings (such as Introduction, Methods, Results, Discussion, Conclusions, etc.) type centered. Side headings in Methods section should include, as appropriate: Participants, Instrumentation, Procedures, and Data Analysis. The Discussion should begin with a very succinct summary of the major conclusions of the paper and then go on to focus on the interpretation and significance of the findings with concise objective comments that describe their relation to other work in the area. It should not repeat information in the results. Side headings in Discussion should include: Study Limitations, Practice Implications, and Research Recommendations. The journal uses US spelling.

Footnotes should be avoided in the main text. When their use is absolutely necessary, footnotes should be numbered consecutively using Arabic numerals and should be typed at the bottom of the page to which they refer. Place a line above the footnote, so it is set off from the text. Use the appropriate superscript numeral for citation in the text.

Author Contributions

Please include a statement delineating the contributions of each author using the criteria recommended by the International Committee of Medical Journal Editors (ICMJE). The statement should mention each author separately by name. ICMJE criteria are:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

If the study includes original data, at least one author must confirm that he or she had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Please include this statement in the cover letter.

Acknowledgements

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Authors should list all funding sources and are responsible for the accuracy of their funder designation. If in doubt, please check the Open Funder Registry for the correct nomenclature: www.crossref.org/services/funder-registry.

If this paper is to be considered for the Journal of Genetic Counseling Best Trainee Paper award, please include a statement indicating that the research presented in the paper was conducted while the first author was in training or to fulfill a degree requirement of the first author. See the Best Trainee Paper Award tab on the journal website for more information about this award. Thanks to anonymous reviewers is not considered appropriate to include in Acknowledgements.

Conflict of Interest Statement

The Conflict of Interest Statement should mention each author separately by name. Recommended wording is as follows:

Author X declares that she has no conflict of interest.

Author Y has received research grants from Drug Company A.

Author Z has received a speaker honorarium from Drug Company B and owns stock in Drug Company C.

If multiple authors declare no conflict, this can be done in one sentence:

Author X, Author Y and Author Z declare that they have no conflict of interest.

Submitting authors should ensure they liaise with all co-authors to confirm agreement with the final statement.

Human Studies and Informed Consent

For manuscripts reporting studies that involve human participants, a statement identifying the ethics committee that approved the study and confirmation that the study conforms to recognized standards is required, for example: Declaration of Helsinki; US Federal Policy for the Protection of Human Subjects; or European Medicines Agency Guidelines for Good Clinical Practice. It should also state clearly in the text that all persons gave their informed consent prior to their inclusion in the study.

The Journal requires that all appropriate steps be taken in obtaining informed consent of any and all human subjects participating in the research comprising the manuscript submitted for review and possible publication, and a statement to this effect must be included in the Human Studies and Informed Consent section of the manuscript. Participant anonymity should be preserved and all identifying information should be excluded in the manuscript.

Photographs need to be cropped sufficiently to prevent human subjects being recognized (an eye bar must not be used because of insufficient de-identification). Images and information from individual participants will only be published where the authors have obtained the individual's free prior informed consent. If any identifying information about participants is included in the article, the following sentence should also be included:

'Additional informed consent was obtained from all participants for which identifying information is included in this article.'

Authors do not need to provide a copy of the consent form to the publisher; however, in signing the author license to publish, authors are required to confirm that consent has been obtained. Wiley has a standard patient consent form available for use.

Animal Studies

The Journal of Genetic Counseling does not publish non-human animal studies. To affirm that this is the case for your submission, please include the following sentence under this subheading in the manuscript:

'No non-human animal studies were carried out by the authors for this article'

References

The accuracy of references is the responsibility of the authors. Only published papers and those in press may be included in the reference list. The Journal has a strong preference against the inclusion of conference abstracts (published or unpublished) or unpublished data in manuscripts. However, if done, unpublished data and submitted manuscripts must be cited parenthetically within the text. Personal communications should also be cited within the text; permission in writing from the communicator is required.

References should be prepared according to the *Publication Manual of the American Psychological Association* (6th edition). The APA website includes a range of resources for authors learning to write in APA style, including an overview of the manual, free tutorials on APA Style basics, and an APA Style Blog. For more information about APA referencing style, please also refer to the APA FAQ.

EndNote users can download the style here.

According to APA style, in text citations should follow the author-date method whereby the author's last name and the year of publication for the source should appear in the text, for example, (Jones, 1998). Multiple citations should be listed alphabetically by author's last name. The complete reference list should appear alphabetically by name at the end of the paper.

Authors should note that the APA referencing style requires that a Digital Object Identifier (DOI) be provided for all references where available. Also, for journal articles, issue numbers are not included unless each issue in the volume begins with page one.

Reference examples follow:

Journal article with fewer than 7 authors

Beers, S. R., & De Bellis, M. D. (2002). Neuropsychological function in children with maltreatment-related posttraumatic stress disorder. *The American Journal of Psychiatry, 159(2),* 483–486. *doi:*10.1176/appi.ajp.159.3.483

Journal article with 7 or more authors

Shelton, B. A., John, D., Gibbs, J. T., Huang, L. N., Ruble, D. N., Martin, C. L., ... Seltzer, M. M. (1996). The division of household labor. *Annual Review of Sociology, 22*, 299–322. *doi:*10.1146/annurev.soc.22.1.299

Note: for more than seven author names list first six with three dots and then last author name.

Book

Bradley-Johnson, S. (1994). *Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school* (2nd ed.). Austin, TX: Pro-ed.

Internet Document

Norton, R. (2006, November 4). How to train a cat to operate a light switch [Video file]. Retrieved from http://www.youtube.com/watch?v=Vja83KLQXZs

Figure Legends

Every figure must have a legend. Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement. Figures should be numbered (with Arabic numerals) and referred to by number in the text.

Additional Files

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. Tables should be numbered (with Arabic numerals) and referred to by number in the text. They should be supplied as editable files, not pasted as images. The table should have a brief explanatory title, and legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in table footnotes. Footnotes should be indicated by superscript lowercase letters and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the table headings. Each table should be on a separate sheet of paper at the end of the submission.

Figures

Authors are encouraged to send the highest quality figures possible. Line art should be exported at 600 dpi or higher, and halftone images should be exported at 300 dpi or higher.

Supporting Information

Supporting information is information that is not essential to the article, but provides greater depth and background. It is hosted online and appears without editing or typesetting. It may include copies of surveys or interview questions, consent forms, tables, figures, videos, datasets, etc.

Click here for Wiley's FAQs on Supporting Information.

Note: if data, scripts, or other artefacts used to generate the analyses presented in the paper are available via a publicly available data repository, authors should include a reference to the location of the material within their paper.

General Style Points

The following points provide general advice on formatting and style.

- **Abbreviations**: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
- **Units of measurement**: Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website for more information about SI units.
- **Numbers**: numbers under 10 should be spelled out, except for: measurements with a unit (8 mmol/L); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).
- **Trade Names**: Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name and the name and location of the manufacturer in parentheses.
- **Genomic Terminology and Nomenclature**: Please use the following terms: genome sequencing instead of whole genome sequencing; exome sequencing instead of whole exome sequencing; pathogenic variant instead of mutation; secondary finding instead of incidental finding. Please italicize gene names; do not italicize protein names. Sequence variants should be described in the text and tables using both DNA and protein designations whenever appropriate. Sequence variant nomenclature must follow the current HGVS guidelines; see varnomen.hgvs.org, where examples of acceptable nomenclature are provided. Human gene nomenclature should follow the standards of the HUGO Gene Nomenclature Committee (HGNC), see https://www.genenames.org/.

- **Pedigrees:** Pedigrees should follow the recommendations for standardized nomenclature accepted by the National Society of Genetic Counselors. Authors should consult the following references for these recommendations:
  - Bennett, R. L. , Steinhaus, K. A., Uhrich, S. B., O' Sullivan, C. K., Resta, R. G. , Lochner-Doyle, D., Markel, D. S., Vincent, V., & Hamanishi, J. (1995). Recommendations for Standardized Human Pedigree Nomenclature. Journal of Genetic Counseling, 4, 267-279.
  - Bennett, R. L., Steinhaus French, K., Resta, R. G., & Lochner Doyle, D. (2008). Standardized Human Pedigree Nomenclature: Update and Assessment of the Recommendations of the National Society of Genetic Counselors. Journal of Genetic Counseling, 17, 424-433.

Return to Guideline Sections

5. EDITORIAL POLICIES AND ETHICAL CONSIDERATIONS

Peer Review and Acceptance

The acceptance criteria for all papers are the quality and originality of the research and its significance to journal readership and the practice and discipline of genetic counseling. Papers will only be sent to review if the Editors determine that the paper meets the appropriate quality and relevance requirements.

Except where otherwise stated, manuscripts are single-blind peer reviewed. Wiley's policy on the confidentiality of the review process is available here.

Data Sharing and Data Accessibility

The Journal encourages data sharing wherever possible, unless this is prevented by ethical, privacy, or confidentiality matters. Authors publishing in the journal are therefore encouraged to make their data, scripts, and other artefacts used to generate the analyses presented in the paper available via a publicly available data repository; however, this is not mandatory. If the study includes original data, at least one

author must confirm that he or she had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Although it would be rare for a paper submitted to the Journal of Genetic Counseling to report novel nucleotide sequence data, should that be the case, the novel nucleotide sequence data including genetic mutations must be submitted to a public database prior to publication and a sentence naming the database should be included in the manuscript.

Human Studies and Subjects

For manuscripts reporting studies that involve human participants, a statement identifying the institutional review board/human investigations committee/ethics committee that approved the study and confirmation that the study conforms to recognized standards is required. It should also state clearly in the text that all persons gave their informed consent prior to their inclusion in the study.

Patient anonymity should be preserved. Information from individual patients will only be published where the authors have obtained the individual's free prior informed consent. Authors do not need to provide a copy of the consent form to the publisher; however, in signing the author license to publish, authors are required to confirm that consent has been obtained. Wiley has a standard patient consent form available for use if needed.

Clinical Trial Registration

The Journal requires that clinical trials are prospectively registered in a publicly accessible database and clinical trial registration numbers are included in all papers that report their results. Authors are asked to include the name of the trial register and the clinical trial registration number at the end of the Abstract. If the trial is not registered, or was registered retrospectively, the reasons for this should be explained.

Research Reporting Guidelines

Accurate and complete reporting enables readers to fully appraise research, replicate it, and use it. Authors are encouraged to adhere to recognized research reporting standards. The EQUATOR Network collects more than 370 reporting guidelines for many study types, including for:

- Randomized trials: CONSORT
- Observational studies: STROBE
- Systematic reviews: PRISMA
- Qualitative research: COREQ
- Quality improvement studies: SQUIRE
- Study protocols: SPIRIT

Studies reporting on genetic counseling as an intervention should refer to and follow guidelines from:

- Standards for the Reporting of Genetic Counseling Interventions in Research and Other Studies (GCIRS), available here.

Publication Ethics

This journal is a member of the Committee on Publication Ethics (COPE). Read Wiley's Top 10 Publishing Ethics Tips for Authors here. Wiley's Publication Ethics Guidelines can be found here.

Return to Guideline Sections

6. AUTHOR LICENSING

If a paper is accepted for publication, the author identified as the formal corresponding author will receive an email prompting them to log in to Author Services, where via the Wiley Author Licensing Service (WALS) they will be required to complete a copyright license agreement on behalf of all authors of the paper.

For authors signing the copyright transfer agreement

If the OnlineOpen option is not selected the corresponding author will be presented with the copyright transfer agreement (CTA) to sign. The terms and conditions of the CTA can be previewed in the samples associated with the Copyright FAQs.

For authors choosing OnlineOpen

If the OnlineOpen option is selected the corresponding author will have a choice of the following Creative Commons License Open Access Agreements (OAA):

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Self-Archiving Definitions and Policies

Note that the journal's standard copyright agreement allows for self-archiving of different versions of the article under specific conditions. Please click here for more detailed information about self-archiving definitions and policies.

Return to Guideline Sections

7. PUBLICATION PROCESS AFTER ACCEPTANCE

Accepted Articles

All accepted manuscripts are subject to editing. Authors have final approval of changes prior to publication.

Proofs

Once the paper is typeset, the author will receive an email notification with full instructions on how to provide proof corrections.

Please note that the author is responsible for all statements made in their work, including changes made during the editorial process – authors should check proofs carefully. Note that proofs should be returned within 48 hours from receipt of first proof.

Publication Charges. **There are no publication charges for JOGC.**

Color figures. Color figures may be published online free of charge.

Return to Guideline Sections

8. POST PUBLICATION

Access and Sharing

When the article is published online:

- The author receives an email alert (if requested).
- The link to the published article can be shared through social media.

- The author will have free access to the paper (after accepting the Terms & Conditions of use, they can view the article).
- The corresponding author and co-authors can nominate up to ten colleagues to receive a publication alert and free online access to the article.

For additional important information on Wiley's Reuse policy, click here.

Promoting the Article

To find out how to best promote an article, click here.

Measuring the Impact of an Article

Wiley also helps our authors measure the impact of their research through specialist partnerships with Kudos) and Altmetric.

Return to Guideline Sections

9. WILEY AUTHOR RESOURCES

Wiley Author Resources

Manuscript Preparation Tips: Wiley has a range of resources for authors preparing manuscripts for submission available here. In particular, authors may benefit from referring to Wiley's best practice tips on Writing for Search Engine Optimization.

Editing, Translation, and Formatting Support: Wiley Editing Services can greatly improve the chances of a manuscript being accepted. Offering expert help in English language editing, translation, manuscript formatting, and figure preparation, Wiley Editing Services ensures that the manuscript is ready for submission.

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Journal Production:
Stephanie Hill
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Return to Guideline Sections

Author Guidelines updated October 2018.

Appendix B: Social Media Recruitment Blurbs

Blurbs for Social Media (Facebook, Instagram) & Online Parenting Websites for Recruitment




The above photos will be used with the BELOW blurbs:

Social Media Blurbs Version 1, 5 July 2018

1. Have you recently been pregnant? Did you have a blood test to screen for chromosomal abnormalities like Down Syndrome?

Researchers at the University of Newcastle are seeking volunteers to participate in a study investigating non-invasive prenatal testing (e.g. Harmony test) and its impacts on parents. Your experience can make a difference! To find out more, please go to: www.findlab.net.au/NIPT/

2. Have you recently made the decision to terminate your pregnancy? Did the results of prenatal testing contribute to this decision?

Researchers at the University of Newcastle are seeking volunteers to participate in a study investigating non-invasive prenatal testing (e.g. Harmony test) and its impacts on parents. Your experience can make a difference! To find out more, please go to: www.findlab.net.au/NIPT/

Appendix C: Standardized Questionnaires

DASS-21 (Lovibond & Lovibond, 1995)

Please read each statement and select the option which indicates how much the statement applied to you in the week after receiving your prenatal screening results. There are no right or wrong answers. Do not spend too much time on any one statement.

0 = Did not apply to me at all - NEVER
1 = Applied to me to some degree, or some of the time – SOMETIMES
2 = Applied to me to a considerable degree, or a good part of the time - OFTEN
3= Applied to me very much, or most of the time – ALMOST ALWAYS

1. I found it hard to wind down	0	1	2	3
2. I was aware of dryness of my mouth	0	1	2	3
3. I couldn't seem to experience any positive feeling at all	0	1	2	3
4. I experienced breathing difficulty (e.g. excessively rapid breathing in the absence of physical exertion)	0	1	2	3
5. I found it difficult to work up the initiative to do things	0	1	2	3
6. I tended to over-react to situations	0	1	2	3
7. I experienced trembling (e.g., in the hands)	0	1	2	3
8. I felt that I was using a lot of nervous energy	0	1	2	3
9. I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10. I felt that I had nothing to look forward to	0	1	2	3
11. I found myself getting agitated	0	1	2	3
12. I found it difficult to relax	0	1	2	3
13. I felt down-hearted and blue	0	1	2	3
14. I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15. I felt I was close to panic	0	1	2	3
16. I was unable to become enthusiastic about anything	0	1	2	3
17. I felt I wasn't worth much as a person	0	1	2	3
18. I felt that I was rather toucht	0	1	2	3
19. I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)	0	1	2	3
20. I felt scared without any good reason	0	1	2	3
21. I felt that life was meaningless	0	1	2	3

Decisional Conflict Scale (O'Connor, 1995)

Think about the decision you made to undergo prenatal screening. Please how strongly you agree or disagree with each statement in regard to your decision to undergo prenatal screening.

0 = strongly agree 1 = agree 2 = neither agree nor disagree
3 = disagree 4 = strongly disagree

1. I knew which options were available to me	0	1	2	3	4
2. I knew the benefits of each option	0	1	2	3	4
3. I knew the risks and side effects of each option	0	1	2	3	4
4. I was clear about which benefits mattered most to me	0	1	2	3	4
5. I was clear about which risks and side effects mattered most to me	0	1	2	3	4
6. I had enough support from others to make a choice	0	1	2	3	4
7. I chose without pressure from others	0	1	2	3	4
8. I had enough advice to make a choice	0	1	2	3	4
9. I was clear about the best choice for me	0	1	2	3	4
10. I felt sure about what to choose	0	1	2	3	4
11. The decision was easy for me to make	0	1	2	3	4
12. I felt I had made an informed choice	0	1	2	3	4
13. My decision showed what is important to me	0	1	2	3	4
14. I expected to stick with my decision	0	1	2	3	4
15. I am satisfied with my decision	0	1	2	3	4

Genetic Counselling Satisfaction Scale (DeMarco, Peshkin, Mars, & Tercyak, 2004)

Please read each statement below and select the how much you agree or disagree with each statement regarding your genetic counselling experience.

*Genetic counselling involves the provision of objective information about NIPT, what it screens for, its clinical features (variability of conditions tested), and the accuracy of the test. Genetic counselling also involves the provision of objective information in regard to the neurodevelopmental disorders that NIPT screens for.

*In the following questions, genetic counsellor refers to the health professional that delivered information about the screening test.

1 = strongly disagree 2 = somewhat disagree 3 = uncertain
4 = somewhat agree 5 = strongly agree

1. My genetic counsellor seemed to understand the stresses I was facing	1	2	3	4	5
2. My genetic counsellor helped my identify what I needed to know to make decisions about what would happen to me	1	2	3	4	5
3. I felt better about my health after meeting with my genetic counsellor	1	2	3	4	5
4. The genetic counselling session was about the right length of time I needed	1	2	3	4	5
5. My genetic counsellor was truly concerned about my wellbeing	1	2	3	4	5
6. The genetic counselling session was valuable to me.	1	2	3	4	5

Appendix D: Demographic Questions

1. What is your current age in year?
    a. [participant entered age]

2. What is your sex?
    a. Male
    b. Female
    c. I would prefer not to disclose
    d. Other (please specify)

3. What is your total yearly household income?
    a. $0 - $18, 200
    b. $18, 201 - $37, 000
    c. $37, 001 - $80, 000
    d. $80, 001 - $180, 000
    e. $180, 001 and over

4. What is your highest level of education?
    a. Year 10 or less
    b. Year 12 or equivalent
    c. Diploma
    d. Bachelor degree
    e. Postgraduate degree

5. Do you have any diagnosed mental health conditions?
    a. Yes (please specify)
    b. No

6. What your most recent pregnancy planned?
    a. Yes
    b. No

7. Were you offered any prenatal screening* at any time during your most recent pregnancy? (*prenatal screening tests your baby's overall development and checks to see if your baby is at risk of genetic conditions, such as Down syndrome)
    a. Yes
    b. No [exited out of survey]
    c. I don't know [exited out of survey]

8. Which prenatal screening test(s) did you undertake?
   Note: Combined First trimester Screening (CFTS) involves ultrasound and a maternal serum blood test for the purpose of screening for early-onset pre-eclampsia and fetal abnormalities such as Down Syndrome. This is usually conducted at 10-13 weeks gestation. This test is Medicare funded.
   Non-Invasive Prenatal Testing (NIPT) involves a blood test for the purpose of screening for fetal abnormalities such as Down syndrome. This test has a higher accuracy rate than the CFTS (at 99% accuracy for Down syndrome). This test is NOT Medicare funded.
   a. Combined First Trimester Screen only
   b. Non-invasive Prenatal Testing only
   c. Combined First Trimester Screening AND Non-Invasive Prenatal Screening
   d. Other [free text]
   e. I don't know [exited out of survey]
   f. None

9. Did you know the difference between non-invasive prenatal testing (NIPT) and combined first trimester screening (CFTS) before beginning this survey?
   a. Yes
   b. No

Note: The following questions are about women's prenatal screening tests. Women who underwent both CFTS and NIPT, were asked questions about both tests, with wording adjusted within survey.

10. Why were you offered prenatal screening for your most recent pregnancy?
    a. Increased risk of fetal anomaly
    b. Standard practice
    c. Recommended by a health professional
    d. Testing was conducted without an explanation
    e. Other (please specify)

11. How long has it been since your prenatal screening?
    a. Less than one month
    b. 1 – 3 months
    c. 3 – 6 months
    d. 6 – 12 months
    e. More than 12 months

12. How long did it take for you to be made aware of your prenatal screening results?
    a. Less than 1 week
    b. 1 – 2 weeks
    c. More than 2 weeks
    d. I have not yet received my results

13. Who delivered your prenatal screening result?
    a. Geneticist
    b. Genetic counsellor
    c. Neonatologist
    d. General Practitioner
    e. Midwife
    f. Nurse
    g. Obstetrician
    h. I don't know
    i. Other (please specify)

14. How was the outcome of your prenatal screening result delivered to you? Please select all applicable options.
    a. Face to face (verbal information only)
    b. Face to face (verbal and written information)
    c. Email
    d. Over the phone
    e. Post
    f. Other (please specify)

15. Did you receive a high-risk/positive result for a fetal anomaly?
    a. Yes
    b. No
    c. I don't know

16. Were you offered any further follow-up testing to confirm your prenatal screening result?
    a. Yes (please specify)
    b. No
    c. I don't know

Note: The following questions were only asked to women who had NIPT

17. If you received a high-risk result, what condition was identified by NIPT?
    a. 22q11.2 deletion syndrome
    b. Down syndrome
    c. Edwards syndrome
    d. Patau syndrome
    e. Turner syndrome
    f. Triple X syndrome
    g. Klinefelter syndrome
    h. Other (please specify)
    i. Not known/disclosed

18. Did you have follow-up diagnostic testing to confirm your NIPT result?
    a. Ultrasound (specific for visual examination of physical abnormalities)
    b. Diagnostic testing (CVS, amniocentesis, or other diagnostic test)
    c. I did not have follow-up testing
    d. Other (please specify)

Note: The follow questions were only asked to those who did have follow-up testing

19. Did the follow-up diagnostic testing confirm the NIPT result?
    a. Yes
    b. No

20. After receiving your diagnostic testing results, what decision did you make regarding this pregnancy
    a. I decided to continue with my pregnancy
    b. I decided to terminate my pregnancy
    c. I am still deciding whether to continue or terminate my pregnancy

21. At what stage of your pregnancy did you make this decision?
    a. 1 – 12 weeks (1st trimester)
    b. 13- 26 weeks (second trimester)
    c. 27 – 40 weeks (third trimester)

Note: The following question was asked to all participants within the survey

22. If you were offered prenatal screening again, would you make the same choice (to undergo screening)? Please elaborate on your response.
    a. Yes [provide elaboration]
    b. No [provide elaboration]

Appendix E: Participant Information Statement

Dr Linda Campbell
School of Psychology
University of Newcastle
Science Offices
Ourimbah
NSW 2258
Ph: (02) 43494404
Linda.e.campbell@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Prenatal Screening Study Information Statement – For Participants
The Impact of Prenatal Screening on Parents

Investigating the Relationship between Prenatal Screening, Informed Decision Making, Counselling and Decision Satisfaction and Psychological Well-being
Dr Linda Campbell, Dr Tracy Dudding, Dr Frida Carswell, Dr Rina Fyfe, Miss Paige Cornell, and Miss Taylah Armstrong

You are invited to take part in a research survey for the project identified above, which is being conducted by Master of Clinical Psychology students Paige Cornell and Taylah Armstrong, under the supervision of Dr Linda Campbell, at the University of Newcastle.

Before you decide whether you would like to take part, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

Why is the research being done?

Researchers at the University of Newcastle are trying to find out more about the experiences of pregnant women following prenatal screening, to better inform the care provided to these women in the future. Prenatal screening tests include non-invasive prenatal testing (NIPT), also known as non-invasive prenatal screening (NIPS), and combined first trimester screening (CFTS). First trimester screening combines the results of biochemical blood tests with the structural findings measured under ultrasound to predict the chance that the baby has a chromosomal or other structural abnormality. In comparison, NIPT is a genetic blood test that analyses the baby's DNA fragments that are circulating in the mother's bloodstream to detect the most common chromosomal abnormalities. By directly analysing the baby's DNA, NIPT results have been shown to be more accurate and have fewer false positives (i.e. abnormal results that are incorrect) than CFTS in identifying Down syndrome cases (Sonic Genetics, 2015).

This study aims to investigate women's satisfaction of their experience with prenatal screening and associated counselling, as well as their psychological wellbeing following the outcomes of the prenatal screening test. This research is expected to inform future health policies regarding the treatment and care of pregnant women, and the provision of information and counselling regarding prenatal screening in Australia.

Who can participate in the research?

Women who have previously been offered prenatal screening are invited to participate in our online survey. Participating in this research is suitable for you if you are fluent in English, as the survey is only available in English.

What choice do you have?

Participation in this survey is entirely voluntary. Should you not wish to take part you may do so without explanation. If you do take part in the survey, you can discontinue the survey at

any time without having to give a reason. If you do discontinue, the questions you have answered may be used in this study. If you received information about this survey from a health care professional, please be assured that your decision regarding participation will not be communicated to your doctor and will not affect your medical treatment or your relationship with staff who are caring for you.

What would you be asked to do if you agree to participate?

If you agree to participate in this study, you will be asked to complete an online survey regarding your experience of prenatal screening. This survey is expected to take approximately 30 minutes. The survey includes questions about your satisfaction regarding the decision to undergo prenatal screening or not, informed choice, and the associated genetic counselling you received. You will also be asked about your personal values, and your psychological wellbeing following this decision. Additionally, demographic questions about your education and income will be asked to establish potential impacts on access to services.

What are the risks and benefits of participating?

Participation in this survey will require you to answer questions about sensitive topics, including your choice to undergo or not to undergo prenatal screening. Additionally, you will be asked questions about your psychological well-being, and satisfaction with your decision making. Some participants may find these topics upsetting, and may experience emotional discomfort and distress as a result of participating.

Should you have any concerns, or feel distressed as a result of participating in this study, please contact your GP, or any of the following services who can provide timely and professional support to people experiencing distress.

Beyond Blue	Lifeline
1300 224 636	13 11 14
www.beyondblue.org.au	www.lifeline.org.au

Will the study cost you anything?

Participation in this study will not cost you anything, nor will you be paid. Participants may find satisfaction in the knowledge that research into experiences following prenatal screening may assist in making important changes regarding care provided to pregnant women in the future.

How will your privacy be protected?

The University of Newcastle is committed to protecting and preserving a participant's right to confidentiality. No personal information will be collected, and questionnaire responses will be collated anonymously. All responses received in the survey will be handled with strict confidentiality. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.
Your unidentified data from this research project will be retained for possible use in future research conducted by other researchers within the University of Newcastle.

What do I do now?

Thank you for reading this information sheet and for considering taking part in this research. If you are happy to participate please follow the link below to continue to the survey.

http://www.findlab.net.au/the-impact-of-prenatal-screening.html

Further Information

Should you have any queries regarding this study, you can contact Linda Campbell using the details provided at the beginning of this statement. If you wish to find out about the results of this study, you can check our website, or follow us on Facebook, with these details being provided below.

Website	Facebook page
www.findlab.net.au	Family Interaction & Neurodevelopmental Disorders Lab

Complaints about this research

This research was reviewed and approved by the Hunter New England Human Research Ethics Committee, Reference number 18/10/17/4.01 Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@hnehealth.nsw.gov.au.

Appendix F: Participant Information Flyer

Have you recently been pregnant?

Have you recently undergone a pre-natal test (non-invasive prenatal testing or combined first trimester screening) to screen for chromosomal abnormalities? We would like to know more about your experience.

We are interested in finding out more about women's decision making, counselling satisfaction, informed choice and psychological well-being following prenatal screening. We invite you to complete an online survey examining these issues.

For more information, and to participate, please follow the link below

http://www.findlab.net.au/the-impact-of-prenatal-screening.html

Participants must have undergone prenatal screening, and be fluent in English. Participation is completely voluntary. All data will remain confidential and anonymous, though may be used for publication. This research may help to improve the care provided to pregnant women in the future.

If you have any further concerns or queries, please visit our website www.findlab.net.au

This research is being conducted by Linda Campbell, Frida Carswell, Tracy Dudding, Paige Cornell, and Taylah Armstrong.

For more information, please contact Linda Campbell (Clinical Psychologist)
linda.e.campbell@newcastle.edu.au

This project has been approved by the Hunter New England Human Research Ethics Committee (Approval number: 2019/ETH01243)

Appendix G: Consent Questions

1. I have read the Information Statement for Participants and consent to participate in this stud.
    a. Yes, I consent to participate in this study
    b. No, I do not consent to participate in this study

2. Do you consent to your unidentified data from this research project to be retained for possible use in future research conducted by the research team at the University of Newcastle?
    a. Yes
    b. No

Appendix H: Ethics Approval

29 November 2018

Dr Linda Campbell
School of Psychology
University of Newcastle

Dear Dr Campbell,

Re: The impact of non-invasive prenatal testing on parents (18/10/17/4.01)

HNEHREC Reference No: 18/10/17/4.01
NSW HREC Reference No: HREC/18/HNE/269

Thank you for submitting the above application for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **17 October 2018.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been certified under the National Health and Medical Research Council's *National Certification Scheme for the Ethical Review of Multi-Centre Human Research*. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and following acceptance of the requested clarifications and revised Information Statements and Survey by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the Committee monitors the research protocols it has approved. **Ethics Approval will be for 5 years and subject to the following conditions:**

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is **November 2019.**
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- Adherence to the safety reporting requirements of the with the NHMRC Safety Monitoring and Reporting Guidance for Therapeutic Goods Trials (November 2016) available at https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.
- If the study has not been completed by **November 2023,** a Renewal Application will be required.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
HREA [Submission Code: AU/1/A298312]		
Project Description	Version 1	12 November 2018
Demographic Questionnaire	Version 2	5 November 2018
Standardised Questionnaires	Version 2	14 November 2018
Reliability and Validity of Standardised Measures	Version 2	9 November 2018
Information Statement – For Health Practitioners	Version 2	12 November 2018
Participant Information Statement	Version 2	12 November 2018
Consent Form (file name Version 1, 9 November 2018)	undated	no date
Recruitment - Social Media Blurbs	Version 1	11 September 2018
Information Pamphlet	Version 2	5 November 2018

Approval has been granted for this study to take place at the following sites:

- **Hunter Genetics**
- **John Hunter Hospital**

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **18/10/17/4.01** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

25 February 2019

Dr Linda Campbell
School of Psychology
University of Newcastle

Dear Dr Campbell

Re: The impact of non-invasive prenatal testing on parents (18/10/17/4.01)

HNEHREC Reference No: 18/10/17/4.01
NSW HREC Reference No: HREC/18/HNE/269
SSA Reference No: SSA/19/HNE/19

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following sites:

- **Hunter Genetics**
- **John Hunter Hospital**

As part of the process of the governance review process for this protocol, the following documents were reviewed for use at the **Hunter Genetics and John Hunter Hospital** site:

Document	Version	Date
Project Description	Version 1	12 November 2018
Demographic Questionnaire	Version 2	5 November 2018
Standardised Questionnaires	Version 2	14 November 2018
Reliability and Validity of Standardised Measures	Version 2	9 November 2018
Information Statement – For Health Practitioners	Version 2	12 November 2018
Participant Information Statement	Version 2	12 November 2018
Consent Form (file name Version 1, 9 November 2018)	undated	no date
Recruitment - Social Media Blurbs	Version 1	11 September 2018
Information Pamphlet	Version 2	5 November 2018

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to the research governance officer;
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to the research governance officer;

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

3. Annual Report submitted to the lead HREC for review and the acknowledgment, are copied to the research governance officer;
4. Final Report submitted to the lead HREC for review and the acknowledgement, are copied to the research governance officer.

Yours faithfully

Dr Nicole Gerrand
Research Governance Officer
Hunter New England Local Health District

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

RESEARCH INTEGRITY UNIT

Registration of External HREC Approval

To Chief Investigator or Project Supervisor:	**Doctor Linda Campbell**
Cc Co-investigators / Research Students:	**Miss Paige Cornell** **Miss Taylah Armstrong** **Dr Tracy Dudding-Byth**
Re Protocol:	**The impact of prenatal testing on parents**
Date:	**27-Mar-2019**
Reference No:	**H-2019-0106**
External HREC Reference No:	**18/10/17/4.01**

Thank you for your **Initial Application** submission to the Research Integrity Unit (RIU) seeking to register an External HREC Approval in relation to the above protocol.

Your submission was considered under an **Administrative Review** by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **External HREC Approval Noted** effective **27-Mar-2019**.

As the approval of an External HREC has been noted, this registration is valid for the approval period determined by that HREC.

Your reference number is **H-2019-0106**.

PLEASE NOTE:
As the RIU has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's RIU, via RIMS.

Linkage of ethics approval to a new Grant

Registered External HREC approvals cannot be assigned to a new grant or award (ie those that were not identified in the initial registration submission) without confirmation from the RIU.

Best wishes for a successful project.

Mr Alan Hales
Manager, Research Compliance, Integrity and Policy

For communications and enquiries:
Human Research Ethics Administration

Research & Innovation Services
Research Integrity Unit

The University of Newcastle
Callaghan NSW 2308
T +61 2 492 17894
Human-Ethics@newcastle.edu.au

RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref

Appendix I: Participation Flowchart

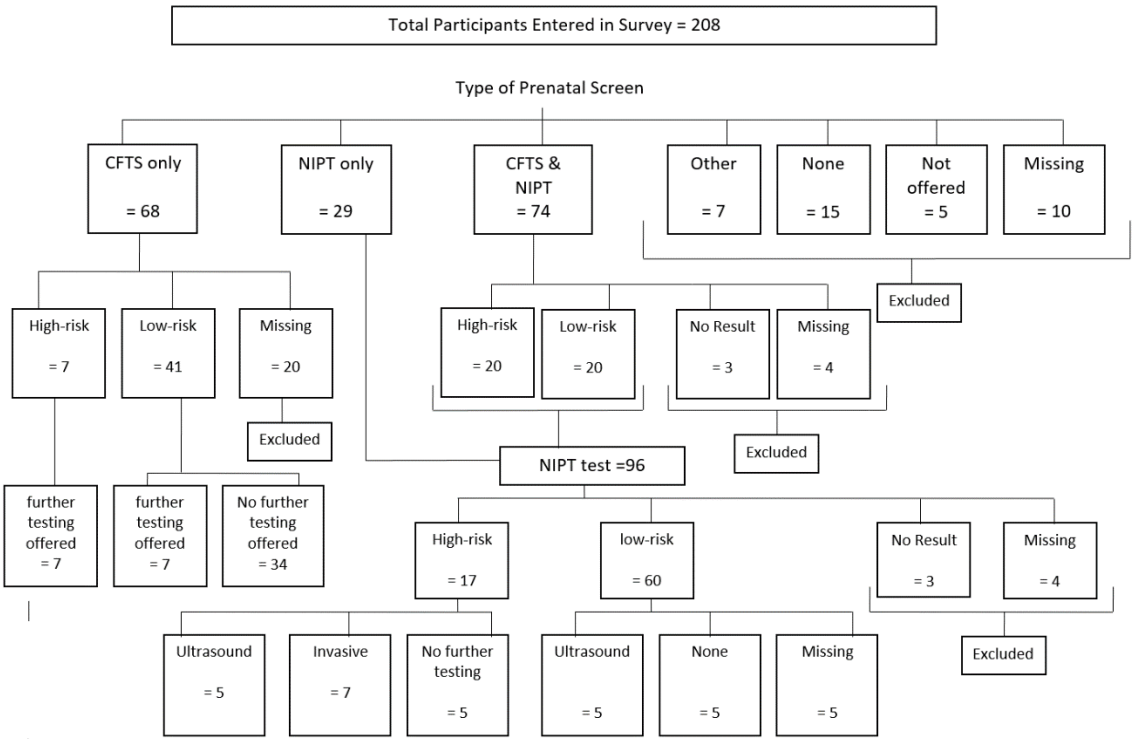

Figure H1. Flowchart showing participant exlucsion and inclusion

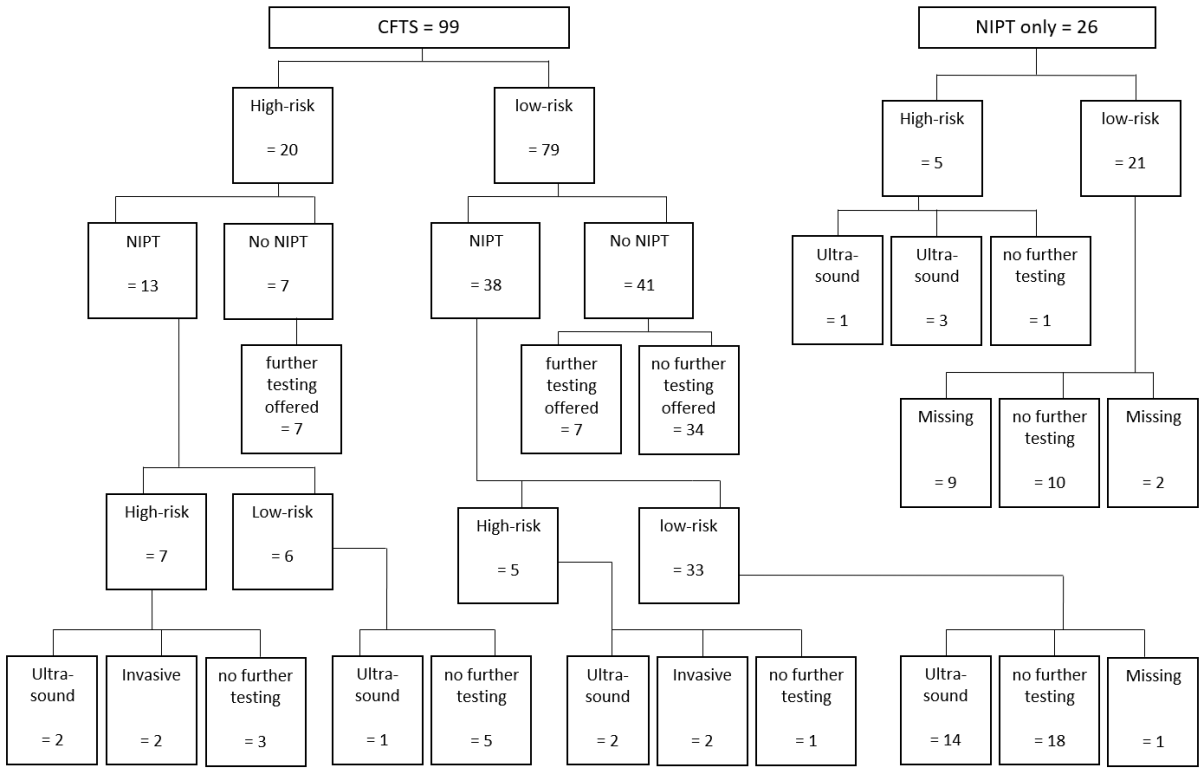

Figure H2. Flowchart showing pathway of prenatal testing