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Psychosocial outcomes from one cohort participating in the STan Australian Randomised controlled Trial (START)

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Abstract

Background: In an Australian randomized controlled trial (RCT), two techniques for intrapartum fetal surveillance were compared: ST analysis (STan) as an adjunct to cardiotocography (CTG), compared with CTG alone. The aim was to determine whether CTG + STan could reduce emergency cesarean birth rates while maintaining or improving neonatal outcomes. Secondary aims were to compare clinical, economic, and psychosocial outcomes. The purpose of this paper was to present psychosocial outcomes from one cohort enrolled in the trial.

Methods: The study was conducted at one tertiary referral hospital. Participants who had taken part in the trial from the outset were invited to complete a questionnaire between March 2018 and January 2020, approximately 8 weeks after giving birth. Outcomes included depression, psychological distress, health-related quality of life, and infant feeding practices. Analysis was by intention to treat.

Results: $N = 207/527$ participants completed the questionnaire ($n = 113$, STan; $n = 94$, CTG alone). Overall, no statistically significant or clinically meaningful differences were found in the two groups for symptoms of depression, psychological distress, quality of life, or infant feeding. A statistically significant difference was observed for the subscale of pain-discomfort, where scores were higher on average in the CTG alone arm relative to that in the CTG + STan arm.

Conclusions: Although STan as an adjunct to CTG constitutes a different clinical technology from CTG alone, both monitoring types appeared to produce similar results in terms of postnatal psychosocial outcomes for women. Findings from this study provide service users and staff with a comprehensive assessment of STan that can be used to make evidence-informed decisions about monitoring options should STan become more widely available.

KEYWORDS
fetal monitoring, psychosocial outcomes, randomized controlled trial

1 | INTRODUCTION

Cardiotocography (CTG) is one of the most common procedures undertaken during labor and has been reported in some settings to be applied in 70% of all labors.[1] Despite being a ubiquitous method of monitoring, this technology has significant shortcomings.[2] In particular, CTG has a false-positive rate (i.e., low specificity) of up to 60% which means that more often than not, it will indicate fetal compromise in cases when it is not present, which can lead to unnecessary interventions such as emergency cesarean delivery.[3] One-third of Australian women now give birth via cesarean,[4] with emergency cesarean delivery rates in some Australian hospitals as high as 18%.[5]

In order to increase specificity and reduce unnecessary interventions, extensive clinical research has led to the development of ST analysis (STan) monitoring technology.[6] STan is used in conjunction with standard CTG monitoring and includes analysis of the ST segment of the fetal electrocardiogram. As such, it may provide additional information with respect to fetal well-being during labor relative to CTG alone, allowing for a more definitive diagnosis of fetal distress and offering considerable potential to reduce unnecessary operative births.[7,8]

CTG can be carried out both externally and internally. The external method collects and records information about the fetal heart rate and woman's contractions using a belt-mounted Doppler and pressure transducers worn around the abdomen.[3,9] When the signal from this external method of CTG is of insufficient quality or is difficult to interpret due to poor signal quality, an internal method can be used which involves the attachment of a fetal scalp electrode (FSE) directly to the fetus. Similar to internal CTG monitoring, STan monitoring requires the placement of the FSE to detect and allow interpretation of the fetal ECG.[7,10] However, unlike CTG, the FSE is always required when using STan monitoring.[7]

In an Australian-first randomized controlled trial (RCT), STan monitoring (CTG + STan), referred to from here on as STan, was compared with CTG monitoring alone to determine whether STan could reduce emergency cesarean birth rates while maintaining or improving neonatal outcomes.[11] In line with the hypothesized reduction in emergency cesarean delivery with STan, a secondary hypothesis was that STan monitoring would result in improved psychosocial outcomes for birthing people.[11,12] In this article, we present findings from the psychosocial outcomes portion of the study for one cohort of women who participated in the trial from the outset.

2 | METHODS

2.1 | Participants and setting

The trial was conducted at the Women's and Children's Hospital, a high-risk specialty facility with approximately 5000 deliveries per annum.[13] Women were eligible for the trial if they were 18 years or older; capable of informed consent; literate in English; and had a singleton fetus in cephalic presentation. Women were excluded from participating if they were <36-week gestation; were planning a cesarean delivery or required a cesarean due to, for example, placenta previa or vasa previa; had contraindications for use of a fetal scalp electrode; had no clinical indication for continuous electronic fetal monitoring; had participated in the study in a previous pregnancy; or if there were known fetal structural or functional cardiac conditions. Consenting participants received continuous fetal monitoring if it was deemed clinically necessary, at which point they were randomized to receive either STan or CTG alone, on an allocation ratio of 1:1 with stratification for parity using a remote phone-based randomization procedure.[11] It should be noted that a sample size calculation was not conducted. This was a pragmatic decision based on feasibility and the fact that the study was exploratory and not powered on a particular outcome.

2.2 | Psychosocial outcomes questionnaire

Between March 2018 and January 2020, women who had taken part in the trial from the outset were sent a precursor invitation letter 6 weeks after giving birth. One week later, a study pack, including a questionnaire, was sent to potential participants. Two methods of responding were offered: (1) a paper questionnaire to be returned by post; or (2) access to an online questionnaire. Tailored reminders (i.e., addressing the woman by her name) were sent to non-responders, including another study pack, approximately 10 weeks after birth, and an SMS was sent approximately 3 weeks after that.

The questionnaire examined psychological and health outcomes, of which postnatal depression, psychological distress, health-related quality of life, and infant feeding are examined in this paper. Scales included as follows: Edinburgh Postnatal Depression Scale (EPDS)[14]; General Health Questionnaire-12 (GHQ-12)[15]; EuroQol-5 dimensions[16]; and Infant Feeding Practices.[17] The questionnaire also included demographic questions.

2.3 | Data analysis

Data were analyzed with the researcher blinded to the identity of treatment group and according to the intention to treat principle. Group differences in means for the following scales were examined by independent-sample *t*-tests: EPDS; EuroQol-5 dimensions (EQ-5D) (measured using a continuous visual analog scale) and GHQ-12 overall scores. Mann–Whitney *U*-tests were run to examine group differences in medians for ordinal data in the GHQ-12 and subscales of the EQ-5D. A chi-squared test for association was conducted between categorical variables randomized group and type of infant feeding. A *p*-value of ≤0.05 was considered statistically significant. Statistical analyses were conducted with SPSS version 19.0.

2.4 | Ethics considerations

Human research ethics approval was gained from both the Women's and Children's Hospital Network Human Research Ethics Committee (HREC/17/WCHN/14) and the University of Adelaide Human Research Ethics Committee. Upon return of the questionnaire, an alert was produced immediately and sent to the primary researcher and research midwife if a woman's score on the EPDS indicated severe depression (above 13 in total) or suicidal ideation (1, 2, or 3 on question 10). The research midwife then contacted these participants and appropriate referrals were made as needed. In addition, in order to minimize potential distress to women, we did not contact those whose infants were admitted to neonatal intensive care (NICU) for an extended period of time.

3 | RESULTS

3.1 | Participants

The questionnaire was sent to $n=527$ potential participants (STan: $n=263$, response rate: 43%; CTG alone: $n=264$, response rate: 36%), after excluding invitations to $n=2$ women whose infants had extended NICU or special care admissions and were only recently discharged from hospital when the questionnaire was due for mailing and to n = 1 woman who withdrew consent for trial participation after randomization (Figure 1). Of the cohort of participants who completed the questionnaire, $n=113$ were randomized to STan (54.9%) and $n=94$ were randomized to CTG alone (45.4%). $N=149$ women completed the questionnaire on paper, and $n=57$ women used the online option (all participants identified as women). Similar

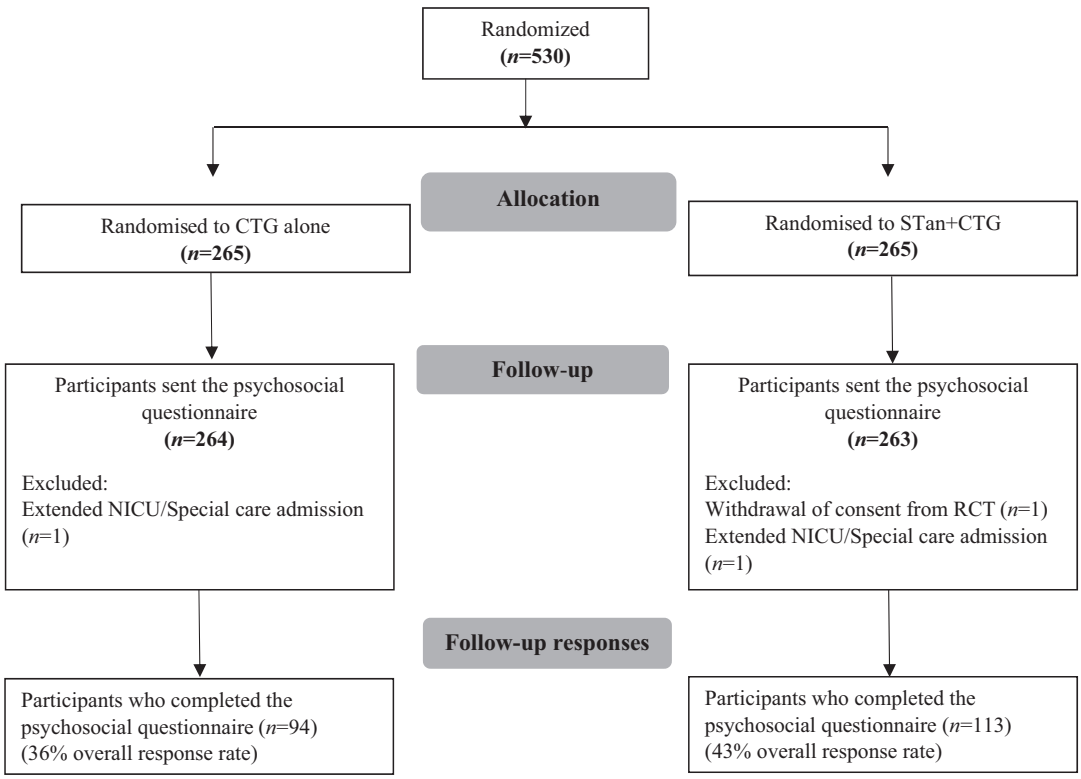

FIGURE 1 Flow of the subset of women from the STan Australian Randomised controlled Trial (START) eligible to participate in the psychosocial study. While non-compliance is anecdotally known to be present, this is not reported in the flow diagram as an intention to treat analysis is intended and participant data will remain blind to researchers until the trial concludes and the main analysis is conducted.

demographic characteristics were observed for those who responded to the questionnaire compared with those who did not. The mean age of responders was 31.80 years (vs 30.29 years for non-responders). The median parity for responders and non-responders in each randomized treatment arm was one. The demographic and clinical characteristics of participants were similar in both arms of the trial; 96.5% of women randomized to STan compared with 71.3% randomized to CTG alone had an FSE (Tables 1 and 2).

3.1.1 | Psychological outcomes

No statistically significant or clinically relevant differences in mean participant scores for women's psychological outcomes were found between the two groups on the EPDS, measuring postnatal depression (Table 3), or the GHQ-12, measuring psychological distress, or on any of the subscales of the GHQ-12 (Table 4).

TABLE 1 Demographic characteristics of women allocated to ST analysis (STan) versus cardiotocography (CTG) alone.

Characteristics	STan (*N* = 113) *n* (%)	CTG alone (*N* = 94) *n* (%)
Marital status		
Married/de facto	102 (90.3%)	86 (91.5%)
Single (family supported)	6 (5.3%)	1 (1.1%)
Single (unsupported)	4 (3.5%)	6 (6.4%)
Language spoken at home		
English	83 (73.5%)	65 (69.1%)
Other language	30 (26.5%)	28 (29.8%)
Education		
Bachelor's degree or higher	61 (54%)	49 (52.2%)
Post-high school training	36 (31.9%)	30 (31.9%)
High school only	15 (13.3%)	13 (13.8%)
Other	1 (0.9%)	2 (2.2%)
Employment		
Full time	53 (46.9%)	42 (44.7%)
Part time	25 (22.1%)	17 (18.1%)
Casual	14 (12.4%)	7 (7.4%)
Not employed	21 (18.6%)	28 (29.8%)
Parity		
1	77 (68.1)	60 (63.8%)
2	25 (22.1%)	23 (24.5%)
3 or more	11 (9.7%)	11 (11.7%)
Age (mean (SD))	31.80 (4.80)	32 (4.62)

3.2 | Physical outcomes

No statistically significant or clinically meaningful differences were found in mean participant scores (measured using a visual analog scale) on the EQ-5D for the two groups (see Table 5). The same was found for subscales of this measure with the exception of the pain-discomfort

TABLE 2 Clinical characteristics of women allocated to ST analysis (STan) versus cardiotocography (CTG) alone.

Characteristics	STan (*N* = 113) *n* (%)	CTG alone (*N* = 94) *n* (%)
Epidural		
Yes	94 (83.3%)	76 (80.9%)
Onset of labor		
Spontaneous	16 (14.2%)	14 (14.9%)
Induced	90 (79.6%)	71 (75.5%)
Augmented	7 (6.2%)	9 (9.6%)
FSE		
Yes	109 (96.5%)	67 (71.3%)

TABLE 3 Postpartum depression scores of women allocated to ST analysis (STan) and cardiotocography (CTG) alone.

Edinburgh postnatal depression scale	STan (*N* = 113) *n* (%)	CTG alone (*N* = 93) *n* (%)
Score		
<9	93 (82.3%)	76 (80.9%)
10–12 (distress)	13 (11.5%)	9 (9.6%)
13 + (major depression)	7 (6.2%)	8 (8.5%)
Item 10 (suicidal ideation)	5 (4.5%)	9 (9.5%)
Mean score (SD)	5.55 (SD = 4.45)	5.58 (SD = 4.84)

TABLE 4 Results of the General Health Questionnaire measuring psychological distress of women.

GHQ-12	STan (*N* = 113) *n*[a] mean (SD)	CTG alone (*N* = 94) *n*[a] mean (SD)
Total score	*n* = 107 10.60 (4.1)	*n* = 92 10.40 (5.07)
Subscales		
Social dysfunction	*n* = 111 5.67 (2.20)	*n* = 94 5.81 (2.69)
Anxiety	*n* = 111 3.80 (1.81)	*n* = 92 3.53 (1.91)
Loss of confidence	*n* = 111 1.17 (0.85)	*n* = 94 1.14 (1.23)

Note: Higher scores indicate lower levels of psychological health.
[a]Numbers vary with missing data for one or more of the subscales.

subscale, reported on at approximately 8 weeks postpartum (see Table 6). The median score on this subscale was statistically significantly higher in the CTG alone arm than in the STan arm $U = 3982.5$, $z = -3.49$, $p = 0.00$. Over 50% of women in both groups were primarily breastfeeding, while 23% of women in the STan group were primarily bottle feeding, compared with 33% of women in the CTG alone group. Overall, no statistically significant differences were found between the two groups in relation to infant feeding (Table 7).

4 | DISCUSSION

This Australian RCT compares the psychosocial outcomes associated with two forms of intrapartum fetal surveillance, STan monitoring and CTG monitoring alone. No previous studies have comprehensively examined the psychosocial outcomes resulting from this mode of monitoring.[10,18–22] The trial was conducted to address the proposition that a hypothesized reduction in emergency cesarean delivery, the primary outcome, would be accompanied by improved secondary outcomes in the form of the psychosocial outcomes reported here.[11] Subsequent to the conceptualization of the trial's hypotheses and before the current study, we conducted a systematic review which indicated that the relationships between emergency cesarean delivery and psychological sequalae are largely confined to outcomes such as posttraumatic stress disorder.[23] This, along with the anecdotal noncompliance in the current trial, may in part explain our results which indicate largely null results, with the exception of increased postpartum pain reported by women in the CTG alone arm. The reason/mechanism behind this finding is not clear, especially given the similarities in the maternal clinical outcomes of the two groups.

The results of this study show that women in both arms experienced very similar outcomes on both psychological measures (postnatal depression and psychological distress) and health measures (health-related quality of life and infant feeding). Findings demonstrated that there was not only similarity between the two groups, but that women appeared to be doing relatively well at around 8 weeks postpartum. For example, in both groups, women rated their overall health above 79/100 on the EQ-VAS where a score of 100 aligns with the best imaginable health state.

TABLE 5 EuroQol-5 dimensions (EQ-5D) scores measuring quality of life of women allocated to ST analysis (STan) and cardiotocography (CTG) alone.

Health status	STan ($N = 112$), mean (SD)	CTG alone ($N = 92$), mean (SD)
EQ-VAS Score	79.61 (11.90)	79.04 (14.34)

Note: Higher scores indicate higher self-reported health status.

TABLE 6 EuroQol-5 dimensions (Q-5D) scores measuring quality of life of women allocated to ST analysis (STan) and cardiotocography (CTG) alone.

Health status	STan ($N = 113$) *n* (%)	CTG alone ($N = 94$) *n* (%)
Mobility		
Level 1 (No problems)	101 (89.4)	78 (83%)
Level 2 (Slight problems)	10 (8.8%)	14 (14.9%)
Level 3 (Moderate problems)	1 (0.9%)	1 (1.1%)
Level 4 (Severe problems)	0	1 (1.1%)
Level 5 (Extreme problems)	1 (0.9%)	0
Self-care problems		
Level 1 (None)	111 (98.2%)	88 (93.6%)
Level 2 (Slight)	2 (1.8%)	5 (5.3%)
Level 3 (Moderate)	0	0
Level 4 (Severe)	0	1 (1.1%)
Level 5 (Extreme)	0	0
Usual activities		
Level 1 (None)	88 (77.9)	67 (71.3%)
Level 2 (Slight)	22 (19.5%)	19 (20.2)
Level 3 (Moderate)	2 (1.8%)	4 (4.3%)
Level 4 (Severe problems)	1 (0.9%)	3 (3.2%)
Level 5 (Extreme problems)	0	1 (1.1%)
Pain-discomfort		
Level 1 (No problems)	71 (62.8%)	37 (39.45)
Level 2 (Slight problems)	38 (33.6%)	48 (51.15)
Level 3 (Moderate problems)	3 (2.7%)	4 (4.3%)
Level 4 (Severe problems)	1 (0.9%)	2 (2.1%)
Level 5 (Extreme problems)	0	3 (3.2%)
Anxiety/Depression		
Level 1 (No problems)	73 (64.6%)	59 (62.8%)
Level 2 (Slight problems)	28 (24.8%)	26 (27.7%)
Level 3 (Moderate problems)	12 (10.6%)	7 (7.4%)
Level 4 (Severe problems)	0	1 (1.1%)
Level 5 (Extreme problems)	0	1 (1.1%)

TABLE 7 Infant feeding practices of women allocated to ST analysis (STan) and cardiotocography (CTG) alone.

Type of infant feeding	STan ($N = 112$) *n* (%)	CTG alone ($N = 93$) *n* (%)
Primarily breastfeeding	66 (58.4%)	52 (55.3%)
Mixed feeding	20 (17.7%)	10 (10.6%)
Primarily bottle feeding	26 (23%)	31 (33%)

Notwithstanding the comparable postnatal depression scores in each group, participants in this study sample who were deemed at higher clinical risk are likely more prone to postnatal depression. In a recent retrospective Australian cohort study of over 50,000 participants,[24] 3.3% of women had probable postnatal depression (scores of 13 or more on the EPDS) when assessed before 6 weeks postpartum, 2 weeks earlier than in the present study. Using the same measure and cut-off scores, this compares with 6.2% of women in the STan group and 8.5% of the CTG alone group. Similarly, about 10% of women in our study (STan: 11.5%; CTG: 9.6%) scored as experiencing postnatal distress (a score of 10–12 on the EPDS), compared with 5.3% of women in the retrospective study.[24]

4.1 | Strengths and limitations

One of the main strengths of the current study is the use of validated measures including the EPDS, GHQ-12, and EQ-5D. At the same time, despite providing women with different options for completing questionnaires (post and online) and making multiple personalized contacts through mail and mobile reminders, response rates were lower than anticipated. In keeping with our experience, research has shown a significant decline in response rates to surveys over the last few decades,[25] particularly in the field of maternal and infant health.[26] Despite this low response rate, selected characteristics of questionnaire responders appeared to be comparable to those of non-responders, suggesting that while generalizability may have been influenced, internal validity was probably reasonable. It is important to recognize that women's decisions to participate in the follow-up questionnaire may have been influenced by their experience in the trial and postnatal psychosocial well-being, potentially introducing the risk of bias. We also acknowledge demand characteristics, in that some of the researchers may have been involved in a woman's care and this could have unintentionally influenced their decision to take part in the follow-up questionnaire. Furthermore, while the single statistically significant finding is to be duly noted, we acknowledge that no corrections for multiple testing were made for our many tests of comparison.

5 | CONCLUSION

This study has presented the psychosocial outcomes for a cohort of women who participated in a RCT comparing two techniques for intrapartum fetal surveillance, one of which is new to Australian maternity care. STan as an adjunct to CTG and CTG alone appears to produce similar psychological and health outcomes for women on measures of postnatal depression, psychological distress, health-related quality of life, and infant feeding. These findings will subsequently be interpreted in conjunction with the clinical outcomes of the trial once it has concluded. If STan is to be implemented in the Australian context, policymakers can be assured that this type of monitoring results in, at the very least, comparable psychosocial outcomes for service users.

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CONFLICT OF INTEREST STATEMENT

There are no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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