

# Telehealth Home Monitoring and Postcardiac Surgery for Congenital Heart Disease

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abstract

**OBJECTIVES:** To test the effect of a 4-month telehealth home monitoring program (REACH), layered on usual care, on postdischarge outcomes in parents of infants recovering from cardiac surgery and their infants.

**METHODS:** Randomized trial of infants discharged from the hospital after cardiac surgery for congenital heart disease. Consecutive infants with complex congenital heart disease undergoing cardiac surgery within 21 days of life were enrolled at 3 university-affiliated pediatric cardiac centers.

**RESULTS:** From 2012 to 2016, 219 parent-infant dyads were enrolled; 109 were randomly assigned to the intervention group and 110 to the control group. At 4 months postdischarge, parenting stress was not significantly different between groups (total Parenting Stress Index in the intervention group was 220 and in the control group was 215;  $P = .61$ ). The percentages of parents who met posttraumatic stress disorder (PTSD) criteria and parent quality of life inventory scores were also not significantly different between the 2 groups (PTSD in the intervention group was 18% and was 18% in the control group;  $P = .56$ ; the mean Ulm Quality of Life Inventory for Parents in the intervention group was 71 and was 70 in the control group;  $P = .88$ ). Infant growth in both groups was suboptimal (the mean weight-for-age z scores were  $-1.1$  in the intervention group and  $-1.2$  in the control group;  $P = .56$ ), and more infants in the intervention group were readmitted to the hospital (66% in the intervention group versus 57% in the control group;  $P < .001$ ).

**CONCLUSIONS:** When added to usual care, the REACH intervention was not associated with an improvement in parent or infant outcomes. Four months after neonatal heart surgery, ~20% of parents demonstrate PTSD symptoms. Suboptimal infant growth and hospital readmissions were common.



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Deidentified individual participant data (including data dictionaries) will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available after publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be submitted to medoff@upenn.edu.

**WHAT'S KNOWN ON THIS SUBJECT:** Parents of infants who undergo cardiac surgery in the neonatal period experience significant stress especially when transitioning home. Home monitoring programs have not been prospectively evaluated. Inclusion criteria for current monitoring programs have been limited to infants with single ventricle physiology.

**WHAT THIS STUDY ADDS:** In this randomized clinical trial, parent stress and the occurrence of posttraumatic stress disorder remained high, and suboptimal infant growth and hospital readmissions were common. Using an intensive telehealth monitoring program did not reduce parental stress or improve infant outcomes.

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Congenital heart disease (CHD) is the most common birth defect, affecting >32 000 infants born each year in the United States.<sup>1</sup> Of every 1000 live births of infants with CHD, 2.3 infants will undergo cardiac intervention in infancy.<sup>2</sup> Parents of infants with complex CHD requiring surgical or catheter-based intervention are under extreme stress during their infant's diagnosis and cardiac intervention. The stress of caring for these infants may last for weeks, months, and often years, placing parents at risk for diminished social, physical and psychological well-being, including posttraumatic stress disorder (PTSD)<sup>3</sup> and diminished quality of life (QoL).<sup>4,5</sup> Mothers, in particular, report psychological distress that manifests as anxiety, sleeplessness, and social dysfunction.<sup>6</sup> In addition, these mothers often demonstrate inadequate styles of coping, such as being less active in problem-solving tasks than mothers with healthy children.<sup>7,8</sup>

Technological advances now are used to provide the opportunity to extend patient monitoring from hospital to home.<sup>9,10</sup> The use of home monitoring programs in infants with single ventricle (SV) CHD has been associated with improved interstage survival. In addition to being used to improving infant outcomes, it is plausible that these home monitoring programs may be used to provide the support necessary to improve parent outcomes. We conducted a randomized trial to test the effect of a 4-month telehealth home monitoring program (REACH) on postdischarge outcomes in parents and their infants with critical CHD. We hypothesized that when added to usual care, families randomly assigned to the REACH intervention would demonstrate better parent outcomes, including reduced parenting stress, fewer parents screening positive for PTSD, and improved QoL, as well as better infant

outcomes, including growth and fewer readmissions 4 months after hospital discharge.

## METHODS

This randomized clinical trial was conducted between 2012 and 2016 at 3 university-affiliated pediatric cardiac centers. Parent-infant dyads were randomly assigned to receive the REACH intervention or usual care. Randomization was performed by using a permuted-block design stratified by SV and biventricular physiology. The study was approved by each center's institutional review board and written informed consent was obtained from each participating parent.

### Subject Population

Infants with complex CHD (Risk Adjustment for Congenital Heart Surgery [RACHS-1] category<sup>11</sup>  $\geq 2$ ) were included if they underwent cardiac surgery during the first 21 days of life and were expected to be discharged from the hospital within the first 2.5 months of life. We excluded infants with genetic disorders and other syndromes (except DiGeorge syndrome) and/or cardiomyopathy and/or those awaiting heart transplant. Primary caregivers were included if the family had a cellphone or home Internet access, were English speaking and reading, and were  $\geq 18$  years of age. Parents were approached for consent after their infant had undergone surgery and was extubated. Mothers were enrolled primarily, unless the father was the primary care provider.

### Intervention

All families in both treatment groups were discharged from the hospital with a digital scale, pulse oximeter, and access to an online educational Web site. All families were instructed to record their infant's weight, caloric intake, oxygen saturation, and heart rate daily. All families received usual postdischarge care; specifically,

infants with biventricular physiology were scheduled for a follow-up visit within 2 weeks after hospital discharge, and infants with SV physiology were managed by the SV home monitoring program at each center. Included in the SV home monitoring program were a weekly phone review by an advanced practice nurse (APN) of daily weight, caloric intake, oxygen saturation, and heart rate, access to the APN as needed, and once or twice monthly cardiology visits alternating with visits with the pediatrician. "Red flags," which indicated that there was a significant change in the infant's status and should be addressed, were predefined by the SV home monitoring program. The SV home monitoring programs at all 3 recruiting sites had at minimum the inclusions noted.

In addition to usual care, REACH intervention primary caregivers received a daily text message, e-mail, or phone call with twice weekly videoconferencing with an APN for 4 months after hospital discharge or until readmission for second stage surgery for infants with SV. Each morning for the first month and weekly thereafter, the parents received the automated communication through the Buddy Check Network (Caryl Technologies, Bryn Mawr, PA) asking about the infant's status, including total feeding intake, vomiting during feedings, morning weight, heart rate, oxygen saturation, and activity. The automated communication also inquired whether the parent desired a phone call from the study APN. Red flags, which indicated that there was a significant change in the infant's status and should be addressed were predefined for the REACH intervention protocol. The APN at each site was notified automatically by text when infant data were sent. Parents were contacted by the APN if data did not meet preset criteria for infant stability. The APN triaged any

problems and consulted as needed with an on-call study pediatric cardiologist.

The REACH virtual home visits were conducted twice weekly by study APNs using either FaceTime or Skype. Study protocols were used to detail the content of virtual home visits, which included a review of daily and weekly infant data, answers for parent questions about cardiac and newborn care, reconfirmation of the parents' knowledge of care issues, and decision trees for unscheduled parent calls. To maintain treatment fidelity, the study APNs were trained to conduct the REACH virtual home visits using case-based scenarios, and 20% of all virtual home visits were audited during the weekly team meetings for adherence to study protocols. The full REACH protocol has been published previously.<sup>12</sup>

### Data Collection

Family and infant demographics, medical history, and hospital course variables were extracted from the infant's medical record. Families were given the Posttraumatic Diagnostic Scale (PTDS) and Ulm Quality of Life Inventory for Parents (ULQIE) questionnaires before discharge to be completed during the first 2 weeks at home. End of the study questionnaires were mailed to the family 4 months after hospital discharge. Physiologic data were uploaded to the Buddy Check Network. Biweekly virtual home-visit interviews collected qualitative parental stress and infant status data.

### Outcome Measures and Statistical Analysis

The primary parental outcome was parenting stress as measured by using the Parenting Stress Index (PSI) (long form).<sup>13</sup> The PSI is used to measure parenting stress and comprises 6 child domain subscales and 7 parent domain subscales as well as a total score and a life score. The PSI has norms based on large and

diverse nationally representative samples and has been used extensively in multiple nonclinical and clinical populations. Construct validity, incremental validity, and treatment sensitivity have been rated as excellent.<sup>14</sup>

Secondary parental outcomes included a PTSD screen as measured by using the PTDS,<sup>15</sup> which is a self-report measure based on *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria. QoL was measured by using the ULQIE, which is used to assesses QoL in parents of chronically ill children.<sup>4</sup> The primary infant outcomes were World Health Organization weight-for-age z scores at study completion and number of unplanned hospital readmissions during the study period. Growth failure was defined as weight-for-age z score  $\leq -2.0$ .

Descriptive statistics were used to characterize all parent and infant measures, including demographic, medical history, and hospital course variables. Means and SDs were used to describe continuous variables. Frequencies and percentages were used to describe dichotomous and categorical variables. Differences in demographic and outcome variables were examined between the REACH intervention and control groups by using Fisher's exact tests for categorical variables and 2-sample *t* tests for continuous variables. Secondary analyses were performed within functional SV and biventricular subsets. A Bonferroni adjusted *P* value  $<.017$  was considered statistically significant. All analyses were performed by using SAS version 9.4 (SAS Institute, Inc, Cary, NC).

Assuming 80% power, a Bonferroni corrected type-I error rate of 0.017 to account for 3 primary outcomes (parental stress [total PSI score], infant weight-for-age z score at 4 months, and number of readmissions in each group) with 2-sided 2-sample *t* tests, 108 parent-infant dyads were

needed to detect clinically meaningful differences equal to one-half of a SD in parental stress and infant weight-for-age z score and a 46% reduction in the number of rehospitalizations in the intervention group.

## RESULTS

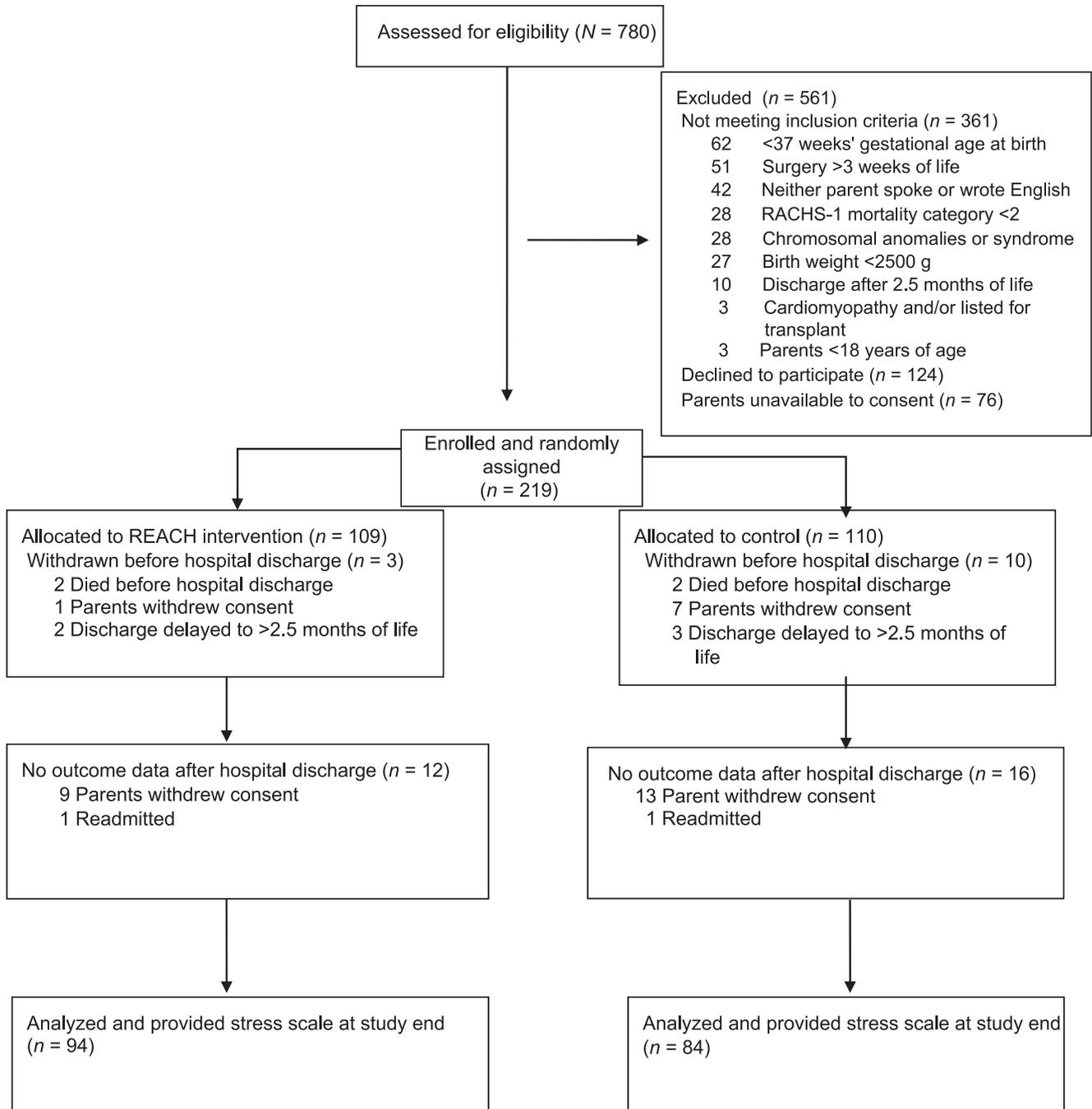
### Trial Enrollment and Protocol Fidelity

Two-hundred nineteen parent-infant dyads were enrolled, which represented 63% of those eligible and available to participate; 109 were randomly assigned to the intervention group and 110 to the control group (Fig 1). The primary reason for not enrolling eligible patients was either parental refusal or parents not available to consent. Outcome data were complete on 178 parent-infant dyads (94 [86%] intervention, 84 [76%] control). Attrition was related to patient deaths before hospital discharge (2 in each group), withdrawal of consent (10 intervention and 20 control patients), and hospital discharge  $>2.5$  months postsurgery (2 intervention and 3 control).

Overall, parents assigned to the REACH intervention ( $n = 94$ ) completed a median of 29 (interquartile range [IQR] 22–34) virtual home visits, 76% of what was expected. Parents of infants with SV CHD ( $n = 52$ ) completed a median number of 28 (IQR 20.5–33) of expected virtual home visits; 16 of 52 parents (31%) completed all virtual home visits. Parents of infants with biventricular CHD ( $n = 42$ ) completed a median number of 32 (IQR 26–35) expected virtual home visits; 19 of 42 (45%) completed all expected visits.

### Study Population

Demographic and medical history data were similar between the 2 groups (Table 1). Most infants were term, male (56%), white (79%), and non-Hispanic (90%). Eighty-one percent had a prenatal cardiac diagnosis with an almost equal



**FIGURE 1**  
Participant enrollment, intervention allocation, and analysis.

number of infants with SV and biventricular congenital heart defects. RACHS-1 mortality category scores were high, with 37% assigned a score of 5 or 6, indicating a cohort with significant CHD complexity. Statistically significant differences in ventricular physiology ( $P < .001$ )

were observed between the treatment groups with a greater proportion of SV infants in the intervention group and a greater proportion of biventricular infants in the control group. No significant differences in the number of unplanned reinterventions, hospital

length of stay, or ventilation days were observed between the 2 groups. Parent participants were primarily mothers (97%) in their thirties, were college educated (53%), and had private insurance (71%). Parents had a median of 2 children in their household (Table 1).

**TABLE 1** Demographic and Medical History

	Intervention (n = 109)	Control (n = 110)	P
<b>Infant data</b>			
Female sex, No. (%)	51 (47)	46 (42)	.46
Gestation age at birth, wk, mean ± SD	38.9 ± 0.1	38.8 ± 0.1	.73
Infant race, No. (%)			.11
White	91 (83.5)	82 (74.5)	
Black	11 (10.1)	17 (15.5)	
Asian	1 (0.9)	2 (1.8)	
Mixed	4 (3.7)	4 (3.6)	
Other	2 (1.8)	0	
Unknown or not reported	0	5 (4.5)	
Infant ethnicity, No. (%)			.81
Hispanic	12 (11.0)	11 (10.0)	
Non-Hispanic	97 (89.0)	99 (90.0)	
RACHS-1 mortality category, No. (%)			.81
1	0 (0)	0 (0)	
2	10 (9.4)	10 (9.5)	
3	37 (34.1)	29 (26.7)	
4	21 (19.4)	29 (26.4)	
5	2 (2.4)	2 (2.0)	
6	38 (34.6)	39 (35.5)	
Ventricular physiology, No. (%)			<.001
SV	56 (51.4)	55 (50.0)	
Biventricular	53 (48.6)	55 (50.0)	
Birth wt, g, mean ± SD	3375.4 ± 43.8	3365.0 ± 40.1	.86
Birth length, cm, mean ± SD	49.4 ± 0.2	50.0 ± 0.3	.05
Head circumference, cm, mean ± SD	34.0 ± 0.2	34.0 ± 0.2	.78
Timing of cardiac diagnosis, No. (%)			.50
Prenatal	91 (83.5)	87 (79.1)	
PredischARGE from newborn nursery	12 (11)	18 (16.4)	
Postdischarge	6 (5.5)	5 (4.5)	
Hospital course, No. (%)			
ECMO use	5 (4.4)	7 (6.4)	.43
Cardiac arrest	9 (8.1)	5 (4.3)	.32
Unplanned reintervention	2 (0.2)	2 (0.4)	.10
Days of mechanical intervention, median (IQR)	3 (2–6)	3 (2–7)	.45
Hospital length of stay, d, median (IQR)	20 (13–27)	18 (14–29)	.94
<b>Parent data</b>			
Female sex, No. (%)	105 (96)	108 (98)	.4
Age, y, mean (SD)	30 (0.5)	30 (0.6)	.96
Education level, No. (%)			.66
College	60 (55.0)	60 (50.8)	
Less than college	33 (30.3)	40 (36.1)	
Not reported or unknown	16 (14.7)	14 (13.1)	
Household income, No. (%)			.17
\$0–\$49 999	33 (30.3)	25 (22.7)	
\$50 000–\$99 999	33 (30.3)	25 (22.7)	
≥\$100 000	22 (20.2)	31 (28.2)	
Not reported or unknown	21 (19.3)	29 (26.4)	
Insurance type, No. (%)			.12
Nonprivate or government funded	37 (33.9)	25 (22.7)	
Not reported or unknown	0 (0)	1 (0.9)	
Private	72 (66.1)	84 (76.4)	
No. children in household, median (IQR)	2 (1–3)	2 (1–3)	.69

ECMO, extracorporeal membrane oxygenation.

## Outcomes

There were no significant differences in parenting stress between the 2 groups (see Table 2). At the end of the study, 18% of parents in both groups

met criteria for PTSD. The mean total symptom severity score was 10 ± 1. There were no significant differences in parent QoL between groups (*P* = .88). For all parents, the mean ULQIE score (76 ± 13) was comparable to

the scores of parents of children with developmental disabilities.<sup>3</sup>

In total, 65 infants (30%) exhibited growth failure at the end of the study. There were no statistically significant differences in growth failure between treatment groups (25% for the intervention group versus 34% for the control group; *P* = .26).

Biweekly virtual home visits and end of study interviews revealed high levels of stress and anxiety in parents. Parents described their worries about their infant's health, lack of weight gain, and impending second stage surgery for the SV infants as well as daily management tasks.

There were significant differences in the number of hospital readmissions between groups. Fewer infants in the control group were readmitted (66% vs 57%), and more infants in the intervention group had >1 hospital readmission (15% vs 7%; *P* < .001).

When several post hoc analyses of parent and infant subgroups were performed, the key findings did not change. Subgroup analyses including SV or biventricular cohort (Tables 3 and 4), race, parental education, income, number of children, weight-for-age z score, number of medications, and feeding mode were performed.

## DISCUSSION

In this prospective randomized trial, we confirmed that the level of stress remains moderately high in parents of infants undergoing surgery for complex CHD. Nearly 20% of mothers met the criteria for PTSD, and their QoL is similar to other parents of children with developmental disabilities and pediatric chronic diseases like cancer.<sup>3</sup> In addition, the infants with complex CHD continue to struggle with slow weight gain after hospital discharge, and one-third experience growth failure. Additional support with a telehealth

**TABLE 2** Parent and Infant Outcomes

	Intervention (n = 109)	Control (n = 110)	P
Parent outcomes			
PSI, mean ± SD			
Total stress	220.0 ± 7.3	215.5 ± 5.2	.61
Child domain	102.4 ± 2.8	98.9 ± 2.5	.34
Distractibility	24.9 ± 0.5	24.6 ± 0.4	.62
Adaptability	26.2 ± 0.9	24.9 ± 0.8	.25
Reinforces parent	9.1 ± 0.4	8.6 ± 0.4	.36
Demandingness	20.1 ± 1.1	19.1 ± 0.6	.44
Mood	10.3 ± 0.4	10.1 ± 0.4	.75
Acceptability	11.8 ± 0.4	11.5 ± 0.5	.69
Parent domain, mean ± SD	117.6 ± 4.8	116.6 ± 3.2	.86
Competence	25.9 ± 1.0	24.2 ± 0.7	.16
Social isolation	13.4 ± 0.8	14.2 ± 0.5	.44
Attachment to child	11.6 ± 0.4	11.0 ± 0.4	.33
Health	12.6 ± 0.5	13.0 ± 0.4	.53
Role restriction	19.8 ± 0.9	19.4 ± 0.6	.75
Depression	17.7 ± 1.0	18.4 ± 0.8	.62
Spouse	16.6 ± 1.0	16.4 ± 0.6	.86
Life stress BV, mean ± SD	7.7 ± 1.0	8.8 ± 1.0	.41
QoL, ULQIE, mean ± SD	70.9 ± 1.7	70.6 ± 1.3	.88
PTSD, met PTSD diagnostic criteria, No. (%)	20 (18.4)	21 (18.8)	.56
Total symptom severity score, mean ± SD	10.1 ± 1.6	10.2 ± 1.2	.95
Symptom cluster scores			
Reexperiencing	3.9 ± 0.6	3.7 ± 0.4	.79
Avoidance	3.5 ± 0.6	3.5 ± 0.5	.99
Arousal	2.8 ± 0.5	3.1 ± 0.4	.62
Infant outcomes			
Wt-for-age z score at study end, mean ± SD	−1.1 ± 0.2	−1.2 ± 0.2	.56
Growth failure (z score ≤ −2.0), No. (%)	26 (24.0)	34 (30.6)	.37
No. readmissions (%)			<.001
0	62 (56.9)	73 (66.4)	
1	30 (27.5)	29 (26.4)	
≥2	17 (15.6)	8 (7.3)	

BV, biventricular.

intervention at home did not improve parent or infant outcomes.

In previous studies, it has been noted that parent anxiety often peaks in the days and weeks after hospital discharge because families typically no longer have immediate access to the supportive nursing and medical staff.<sup>16</sup> Several previous studies revealed that parents of neonates who undergo cardiac surgery experience high levels of stress.<sup>17,18</sup> In these studies, researchers indicate that the demands and anxiety of caring for an infant postcardiac surgery is often overwhelming. This is critically important because long-term parental stress is thought to negatively affect one's capacity to optimally parent both the infant with

CHD and the other children in the household.<sup>8</sup>

This study was based on Brooten's transition to home model of care conceptual model.<sup>19</sup> She reported that premature infants and their families successfully transitioned to home earlier with fewer infant complications and parental stress with the support of APN home visits. We believed that our adapted transition model with the use of telehealth would also decrease maternal stress as a result of the APN interactions during a biweekly "virtual home visits," vigilant infant monitoring, and 24/7 availability. It is difficult to explain the difference in the PSI results, mainly moderate to high average subscales, in comparison to the stress described

during the biweekly virtual home visits (D.A.F., unpublished observations). In focus groups, mothers describe their daily stress levels as often overwhelming.<sup>20</sup> It may be that the PSI was not sensitive enough to capture the stress related to caring for an infant after neonatal heart surgery.

The REACH intervention was used to provide support on a biweekly basis, helping parents cope with an issue or issues that the family was facing at that specific time regarding infant care, particularly feeding and weight gain issues. As reported by families, the use of the REACH intervention decreased stress at a specific time point. However, these intense interactions between parents and the APN over 4 months were not enough to mitigate long-term stress, as measured by using the PSI. Clearly, there is a need for additional alternative interventions, such as counseling or meditation, to further mitigate parental stress and these should be investigated in future studies.

The high rate of PTSD found in our study is consistent with previous investigations.<sup>21</sup> In general, we are unable to determine which parents were at highest risk for PTSD. With further prospective inquiry, we may be able to identify a PTSD phenotype on the basis of a cluster of socio-behavioral variables unrelated to their infants' heart defect. Characterizing this phenotype would allow early identification and targeted supportive interventions in the high-risk group. Until we have these data, all parents of infants with complex CHD should be routinely screened for PTSD, and parents who screen positive for PTSD should be referred for counseling.

Using the ULQIE, Goldbeck et al<sup>4</sup> assessed the QoL of parents of children with CHD ranging from 7 to 20 years old. The parent respondents in our trial in both the intervention

**TABLE 3** Parent and Infant Outcomes for SV Subset

	REACH Intervention (n = 56)	Control (n = 55)	P
Parent outcomes			
PSI, mean ± SD			
Total stress	217.4 ± 4.7	210.9 ± 7.8	.47
Child domain	103.0 ± 2.6	97.8 ± 3.3	.21
Distractibility	24.3 ± 0.5	24.0 ± 0.6	.66
Adaptability	27.3 ± 0.8	25.1 ± 1.1	.11
Reinforces parent	9.4 ± 0.4	8.8 ± 0.6	.40
Demandingness	19.6 ± 0.7	18.7 ± 0.8	.44
Mood	10.4 ± 0.4	9.9 ± 0.5	.50
Acceptability	12.1 ± 0.5	11.3 ± 0.7	.36
Parent domain	114.3 ± 2.8	113.1 ± 4.9	.83
Competence	25.0 ± 0.6	23.8 ± 1.0	.30
Social isolation	12.8 ± 0.5	13.7 ± 0.7	.32
Attachment to child	11.4 ± 0.4	11.1 ± 0.6	.59
Health	12.3 ± 0.4	12.5 ± 0.6	.82
Role restriction	19.0 ± 0.7	18.7 ± 1.0	.76
Depression	17.5 ± 0.6	17.7 ± 1.0	.87
Spouse	16.2 ± 0.7	15.6 ± 0.8	.57
Life stress	7.9 ± 0.9	9.3 ± 1.5	.43
QoL, ULQIE, mean ± SD	71.1 ± 1.3	71.4 ± 1.9	.90
PTSD, No. (%)			
Met PTSD diagnostic criteria	12 (21.1)	11 (20.7)	.68
Total symptom severity score, mean ± SD	8.5 ± 1.0	10.3 ± 1.6	.32
Symptom cluster scores			
Reexperiencing	3.1 ± 0.4	3.7 ± 0.6	.39
Avoidance	2.8 ± 0.4	3.4 ± 0.7	.43
Arousal	2.6 ± 0.4	3.2 ± 0.5	.31
Infant outcomes			
Wt-for-age z score at study end, mean ± SD	-1.1 ± 0.2	-1.4 ± 0.2	.47
No. readmissions (%)			.11
0	28 (50.0)	30 (54.5)	
1	15 (26.8)	20 (36.4)	
≥1	13 (23.2)	5 (9.1)	

and control groups rated their own QoL similarly to the German parents of children with CHD in the original validation study. The parent respondents in our study reported a decrease in QoL, like that of parents of children with cancer and cystic fibrosis. The high levels of stress described by our families likely contributed to the lower QoL scores noted. Given the lack of effectiveness of our intervention on parent stress, it is not surprising that there was no difference in QoL between the intervention and control groups.

The REACH intervention was novel for infants with CHD.<sup>12</sup> The telehealth platform performed well, facilitating automated and timely transmission of clinical data between parents and study APNs. This study reveals the feasibility of performing virtual home

visits by using widely available telecommunication products in the infant CHD population. Previous home monitoring programs were clinical demonstration programs aimed at improving infant weight gain and reducing infant mortality.<sup>21,22</sup>

Contrary to our hypothesis, the REACH intervention did not reduce parental stress or PTSD, improve the parent's QoL, or improve infant somatic growth or reduce infant readmission rates. The duration of intervention may have been too short, or the frequency of contacts during the intervention may have been too infrequent. We questioned whether implementing the intervention decreased the burden of home decision-making with the availability of the APNs or imposed more of a burden. We hypothesized that

families of infants with SV would benefit the most from participating in REACH, but this was not supported by using our findings. The home monitoring for SV infants in the control group was more intense than the standard of care for infants with biventricular physiology, which may explain similar infant outcomes. The heterogeneity of the biventricular group, with more infants with less complicated postdischarge care demands, may have diluted the benefits of the REACH intervention in this group.

We considered a number of issues that may have contributed to the negative findings of this trial. Given that outcomes were nearly identical between treatment groups, we do not anticipate that these findings would change with a larger sample size. Drop-out rates were low, and compliance with the intervention was good. It is possible that the additional burden of data collection and communication required of parents assigned to the REACH intervention group adversely impacted stress and QoL. Furthermore, although most clinicians are likely reassured by serial data measurement in their patients, it is possible that parents may have greater anxiety and feel a greater burden when obtaining serial clinical information on their own infant. Additionally, although parents assigned to the intervention group were reassured by easy and frequent access to the study APNs, APNs do not have formal education in psychological counseling and stress reduction techniques. Interventions with a strong focus on parental counseling should be included in future studies.

We believe the higher readmission rates in the intervention group were due to the strict guidelines for evaluation (red flags) in the REACH intervention protocol. The advantage of the Buddy Check Network was that the APN was notified immediately when data were received, and the

**Table 4** Parent and Infant Outcomes for Biventricular Subset

Parent Outcomes	Intervention (n = 53)	Control (n = 55)	P
Parental Stress Index, mean ± SD			
Total stress	222.8 ± 14.2	220.1 ± 6.3	.86
Child domain	101.8 ± 5.2	100.0 ± 3.4	.76
Distractibility	25.6 ± 0.9	25.2 ± 0.6	.73
Adaptability	25.0 ± 1.4	24.7 ± 1.1	.86
Reinforces parent	8.9 ± 0.8	8.4 ± 0.5	.08
Demandingness	20.6 ± 2.0	19.5 ± 0.9	.64
Mood	10.2 ± 0.7	10.4 ± 0.5	.88
Acceptability	11.5 ± 0.7	11.8 ± 0.6	.74
Parent domain	121.1 ± 9.5	120.1 ± 3.6	.92
Competence	26.9 ± 2.0	24.5 ± 0.9	.28
Social isolation	14.1 ± 1.6	14.6 ± 0.7	.74
Attachment to child	11.7 ± 0.7	11.0 ± 0.5	.36
Health	12.9 ± 0.8	13.5 ± 0.5	.54
Role restriction	20.5 ± 1.7	20.2 ± 0.8	.86
Depression	18.0 ± 1.8	19.1 ± 1.0	.6
Spouse	16.9 ± 1.9	17.1 ± 0.8	.92
Life stress	7.6 ± 1.7	8.3 ± 1.2	.71
QoL, mean ± SD			
Ulm Quality of Life Inventory for Parents	70.8 ± 3.2	69.8 ± 2.1	.82
Posttraumatic Diagnostic Scale			
Met PTSD Diagnostic Criteria, No. (%)	8 (15.7)	9 (16.9)	.54
Total symptom severity score, mean ± SD	11.9 ± 3.0	10.2 ± 1.6	.60
Symptom cluster scores			
Re-experiencing	7.5 ± 1.6	7.2 ± 0.8	.87
Avoidance	4.7 ± 1.1	3.7 ± 0.6	.42
Arousal	4.2 ± 1.2	3.5 ± 0.7	.63
Infant outcomes			
Weight-for-age z-score at study end, mean ± SD	-1.0 ± 0.3	-1.1 ± 0.3	.83
Number of readmissions, No. (%)			.26
0	34 (64.2)	43 (78.2)	
1	15 (28.3)	9 (16.4)	
≥2	4 (7.5)	3 (5.5)	

PTSD, post-traumatic stress disorder; SD, standard deviation.

data were, therefore, evaluated daily. Likewise, if the daily data were not received when expected, parents were also contacted to make sure all was well. All of the readmissions were evaluated by the admitting cardiologist to be timely and necessary.

The study was conducted at 3 large pediatric academic cardiovascular centers, and, thus, the findings may not be widely generalizable to all centers. We did not design this study to allow post hoc analysis of who might derive

benefit from a telehealth intervention. It may be that parents who are technologically savvy, those with little extended family support, or those living far from treatment centers might benefit. Most parental participants were mothers, and, thus, we cannot comment on whether using the REACH intervention would influence outcomes in fathers.

### CONCLUSIONS

Using our study results, we confirm that PTSD rates are high in parents of

infants who are recovering from cardiac surgery. The intensive telehealth home care REACH intervention was not associated with improvement in parent or infant outcomes when compared with usual care. Further studies are needed to identify impactful interventions.

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### ABBREVIATIONS

APN: advanced practice nurse  
 CHD: congenital heart disease  
 IQR: interquartile range  
 PSI: Parenting Stress Index  
 PTDS: Posttraumatic Diagnostic Scale  
 PTSD: posttraumatic stress disorder  
 QoL: quality of life  
 RACHS-1: Risk Adjustment for Congenital Heart Surgery  
 SV: single ventricle  
 ULQIE: Ulm Quality of Life Inventory for Parents

Drs Medoff Cooper, Curley, Marino, Ravishankar, Costello, and Hanlon conceptualized and designed the study, drafted the manuscript, and reviewed and revised the manuscript; Drs Goffenshtein, Lisanti, and Huang were responsible for reviewing databases, cleaning the data, and reviewing the manuscript and assisted in the revisions; Dr Fleck was the project manager for the study, coordinated data collection, participated in analysis, drafted sections of the manuscript, and reviewed the drafts of the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

This trial has been registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (identifier NCT01941667).

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