Cover Page

Title: Assessing and Promoting Resilience in Patients With Adult Congenital Heart Disease
NCT number: NCT04738474
Document date: Sept 5, 2025

Contents:
Study Protocol
Statistical Analysis Plan

(Research Coordinator's) Study Protocol <last updated 2023>

Specific Aim: Conduct a randomized pilot clinical trial to evaluate the feasibility and preliminary efficacy of the PRISM intervention among patients with ACHD.

Hypothesis: PRISM will be feasible and improve patient-reported resilience compared to usual care.

Description of PRISM sessions:

Topic	Skills	Format
1. Managing Stress	Mindfulness, Relaxation	One-on-One, In-Person or Video Chat
2. Setting Goals	Setting specific and realistic goals, planning for roadblocks	
3. Positive Reframing	Recognizing and replacing negative self-talk	
4. Making Meaning	Identifying benefits, gratitude, purpose, and legacy	
5. Advance Care Planning	Completion of sections of Voicing My Choices™ advance care planning tool for adolescents and young adults	
6. Coming Together	Discussion of what worked, plans for moving forward	Family Meeting
(i) Boosters/Worksheets	Between-session tools & practice	Individual

Questionnaire Elements:

- EuroQOL Scale (EQ5D-3L): 5-item tool used to assess quality of life (QOL) as it relates to health.
- Linear Analog Scale (LAS): Single item tool used to assess QOL on a continuous 0-100 scale.
- Hospital Anxiety and Depression Scale (HADS): 14-item tool to assess symptoms related to anxiety and depression. It is not intended to diagnose these conditions.
- Kessler-6 Psychological Distress Scale: 6-item inventory measuring the level of global psychological distress.
- Advance care planning (ACP) comfort: 2- question assessment of experience and comfort with ACP
- Connor-Davidson Resilience Scale (CD-RISC 10): 10-item measurement of inherent resiliency, created based on the original 25-item tool. Questions revolve around personal problem-solving and approaches to adversity.
- Perceived Competence Scale (PCS): 4-item tool that asks about one's competence in managing disease

Domain	Measurement Tool	Source & Collection Time
Patient-Centered Outcomes		
Quality of Life	EQ5D-3L & LAS (primary)	Patient; enrollment & 3 months
Psychological Distress	HADS; Kessler-6	Patient; enrollment & 3 months
Self-Efficacy (for health)	PCS	Patient; enrollment & 3 months
ACP Comfort	ACP assessment questions	Patient; enrollment & 3 months
Predictor: Resilience	CD-RISC 10 (primary)	Patient; enrollment & 3 months
Effect Modifier: Health Status	Independence in activities of daily living, presence of heart-related hospitalization in the last year, diagnosis of heart failure	Electronic health record, patient; enrollment

Potential Confounders: Demographics, Social Determinants of Health	Age, sex, race/ethnicity, marital status, education, family structure, residential information, heart lesion severity	Electronic health record, patient; enrollment

General Notes:
RC will keep complete and secure study records and adhere to protocol fidelity
RC will meet with PI **weekly, Thursdays 10am,** to discuss progress and any challenges; RC personal development goals will also be reviewed quarterly
RC will assist in the creation of a secure electronic database and maintain data using REDcap

Study Population:
Adult (18+ years) outpatients receiving care at the UW ACHD clinic
Patients with moderate or complex ACHD, stages C or D (stages A and B excluded; if needed, can expand back to stage B at a later date)
Must be able to participate in study activities independently and in English.
May not have another life-limiting illness or have participated in Aim 2. A life-limiting illness includes any illness known to be acutely terminal. Examples are cancer, Alzheimer's dementia, progressive neuromuscular diseases. RC will discuss with PI if uncertain.
If concern for cognitive impairment, patients will be screened with a six-item screening tool (Callahan 2002): 3-item recall [apple, table, penny], 3-item temporal orientation [day of the week, month, year].

Participant Enrollment:
RC will screen electronic patient lists for ACHD outpatient clinics to identify potential study participants.
RC will contact eligible patients (telephone and email), explain the study, and assess interest in participation using study team written and approved recruitment scripts.
If agreeable, patients will be enrolled into the study. RC will obtain informed consent.
Participants will be randomized to either the "intervention" (completion of PRISM) or "usual care" (non-directive, supportive care without PRISM) groups.

Randomization will occur following completion of baseline study measures and in a 1:1 ratio. The unit of randomization is the patient, and the randomization group will be the primary predictor of interest (PRISM or "usual care"). Group assignment will be determined using computerized random numbers with variable block sizes. Assignment will be provided to study staff in sealed, opaque, consecutively numbered envelopes (vs built into REDCap).

Participants and the RC will not be blinded; other staff will be blinded to the extent possible
Anticipated sample size of 60 total participants (30 per group). To achieve complete data for 60 participants, we anticipate enrolling 86 patients, 43 in each arm. Enrollment is anticipated within 9 months, may be extended 2-3 months if needed. Goal is to enroll at least 7 patients per month to reach the 1-year maximum.

Planned Enrollment Report

Racial Categories	**Ethnic Categories**				**Total**
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	

American Indian/Alaska Native	0	1	0	0	1
Asian	8	8	0	0	16
Native Hawaiian or Other Pacific Islander	1	0	0	0	1
Black or African American	2	2	1	1	6
White	24	24	3	3	54
More than One Race	3	4	0	1	8
Total	38	38	5	5	86

Study Measures and Data Collection:

RC will confirm and document contact information for study follow-up at enrollment.

RC will deliver the baseline questionnaire to all participants.

- Questionnaire will be completed either directly in REDCap via an emailed link, or on paper which will then be transcribed by study personnel into REDCap (if transcribed, will be double checked by another team member).
- At least 5 telephone and email attempts will be made to obtain responses, unless patients opt out
- RC will review responses within one week. If any responses suggest severe participant distress (HADS >16 (?) or K6 >12), RC will discuss with PI immediately.

RC will extract additional pertinent demographic information from medical records

- MRN
- Age
- Sex (Gender*)
- Race
- Ethnicity
- Insurance type
- ACHD diagnosis
- ACHD complexity (A&P classifications)
- Diagnosis of heart failure (or Fontan failure)
- Cardiac hospitalization in last year
- Diagnosis of mood or anxiety disorder (anxiety, depression, bipolar, post-traumatic stress disorder)

Usual Care group:

- No interim interventions apart from routine clinical care
- Direct any study questions to the PI
- At 3 months, RC will deliver the 3-mo questionnaire. At least 5 telephone and email attempts will be made to obtain responses, unless patients opt out.
- RC will provide gift cards ($50) to participants ahead of final questionnaire completion.

Intervention group:

- Within 2 weeks of baseline data collection, RC will schedule an initial research visit to introduce PRISM and create a completion plan.
- Patients will subsequently schedule and participate in five 30-50-minute sessions (four core PRISM skills sessions and one ACP session), followed by one 30-50-minute “Coming Together” session with patients and their caregivers. ~~Ideally, the first session is conducted~~

~~in person~~ [changed Jan 2023] Sessions will occur using telephone or video chat. Each subsequent session will occur within 1-2 weeks of the previous session (=intervention completion by 3 months). At least 5 telephone and email attempts will be made to schedule sessions, unless patients opt out.
- After completing PRISM, RC will deliver the 3-mo questionnaire. At least 5 telephone and email attempts will be made to obtain responses, unless patients opt out.
- RC will provide gift cards ($50) to participants ahead of final questionnaire completion. Study-related activities (such as parking; case-by-case basis, discuss with PI) will also be reimbursed.
- RC will conduct “exit interviews” with a subset of PRISM participants (discuss with PI) to gather feedback about the experience/intervention. A modest gift card will be provided to interview participants.

- RC will keep notes on patient interactions and any feedback or comments provided during or related to sessions. This will occur in a separate “PRISM Memos/Feedback” document.

Statistical Analysis Plan

(As Published in *Contemporary Clinical Trials*, October 2024;
https://doi.org/10.1016/j.cct.2024.107638)

Our primary aim is to describe feasibility, defined by the proportion of patients who a) enroll in the study among those who are eligible during the recruitment period, and b) complete the PRISM intervention among those randomized to that arm. We anticipate 70% enrollment and retention rates. We will also gain insight into feasibility from a qualitative content analysis of transcribed exit interview data. We anticipate that transcriptions will be reviewed by two study team members, using an inductively developed coding matrix to identify and organize topics discussed. Finally, the research coordinator and PRISM coach will provide an assessment of feasibility from the interventionist standpoint, summarizing study conduct adaptations and barriers that must be addressed in future studies, or if PRISM were to be implemented at scale in the ACHD population.

Additionally, we will evaluate the efficacy of the PRISM intervention to increase resilience in this population. We will evaluate the difference in mean resilience at 3 months after randomization between participants randomized to PRISM and participants randomized to usual care, following the intent-to-treat principle. We will adjust for resilience score at randomization, via a linear regression model, as resilience at randomization and 3 months later (after the intervention period) will likely be highly correlated and thus the adjustment will improve our precision. In exploratory analyses, we will evaluate the effect of the PRISM intervention on QOL, psychological distress, perceived competence for health care management, and comfort with advance care planning using analogous analyses.