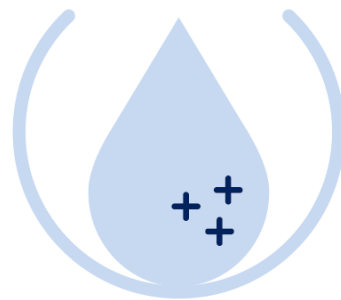


Symptom Monitoring in Dialysis: *SMaRRT-HD Study Overview*



SMaRRT-HD™

Symptom Monitoring in Renal Replacement Therapy-Hemodialysis

Dialysis-related symptoms are important

- Symptoms are of high priority to patients, but symptoms are often under-recognized and under-treated by clinicians.
- Many symptoms occur during hemodialysis treatments.
- Cramps, itching, headache, and post-dialysis fatigue are common.
- High symptom burdens are associated with worse quality of life and higher rates of hospitalization and death.

Symptoms negatively impact patient lives

I can't stand up. Them cramps, they rough. I try not to come off the machine early... I fight it. This probably go against me on the transplant. I'm fighting it, but it ain't no fun to fight.

[68 y.o. hemodialysis patient]

Normally, I'm fatigued, and it's like something's sitting up on your shoulders and you can't wait to get home to lay down. It's terrible.

[58 y.o. hemodialysis patient]

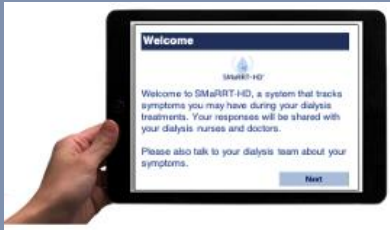
Regular symptom monitoring & follow-up can help

- Clinical trials show that, among people with cancer, regular symptom monitoring with patient surveys and consistent clinician follow-up of symptoms can...
 - **Improve symptoms and quality of life**
 - **Decrease hospitalizations and death**
 - **Deepen patient-clinician communication**

Systems that support symptom reporting and follow-up have not been tested in United States dialysis care.

Symptom Monitoring on Renal Replacement Therapy- Hemodialysis (SMaRRT-HD)

Symptom Survey



- 14 symptom questions *[patients]*
 - 13 symptoms (12 specific + up to 5 free response)
 - Recovery time question (in hours)

Follow-up Supports



- **Email alerts** *[designated RNs, physicians, advanced practice providers]*
- **Symptom reports** *[designated RNs, physicians, advanced practice providers, patients]*
 - Graphs of symptoms from up to the last 8 administrations
- **Symptom guidances** *[physicians, advanced practice providers]*



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Symptom Monitoring in Renal Replacement Therapy - Hemodialysis


Symptom Surveys

- Cramping
- Nausea
- Vomiting
- Dizziness
- Racing heart
- Chest pain
- Shortness of breath
- Thirst
- Headache
- Itching
- Restless legs
- Tingling
- Post-dialysis fatigue
- Write-in symptom(s)

Question 1 of 14

DURING your **LAST** dialysis treatment here, did you have

Cramping?



No Cramping Mild Cramping Moderate Cramping Severe Cramping Very Severe Cramping

English and Spanish offered



SMaRRT-HD™

Symptom Monitoring in Renal Replacement Therapy-Hemodialysis

Clinicians receive Email Alerts for:

- Any report of chest pain, palpitations, shortness of breath
- Severe or very severe report for all other symptoms
- New symptom (not reported in last 3 admin.)

FROM: SMaRRT-HD Research Team (SMaRRT-HD@unc.edu)

TO: mary.nurse@freseniusmedicalcare.com

SUBJECT: SMaRRT-HD Symptom Alert for 3/2/23

EMAIL TEXT:

Dear [*Dialysis Clinician name*],

A patient has reported symptoms that meet the threshold for email notification. The following symptoms occurred during their hemodialysis treatment on **March 2, 2023**:

- **Chest Pain:** Mild
- **Cramping:** Severe
- **New Nausea in last 3 SMaRRT-HD administrations:** Moderate
- **Write-in symptom - Diarrhea:** Severe
- **Time to recovery after dialysis:** 14 hours

Click [symptom report](#) to display the reporting patient and the patient's symptoms over up to the last 8 SMaRRT-HD administrations.

The corresponding symptom guidance(s) for clinicians is here:

- [Chest pain](#)
- [Cramping](#)
- [Nausea](#)
- [Post-dialysis fatigue](#)



SMaRRT-HD™

Symptom Monitoring in Renal Replacement Therapy-Hemodialysis

Symptom Reports for clinicians and patients

John Doe – SMaRRT-HD Research Trial Symptom Report



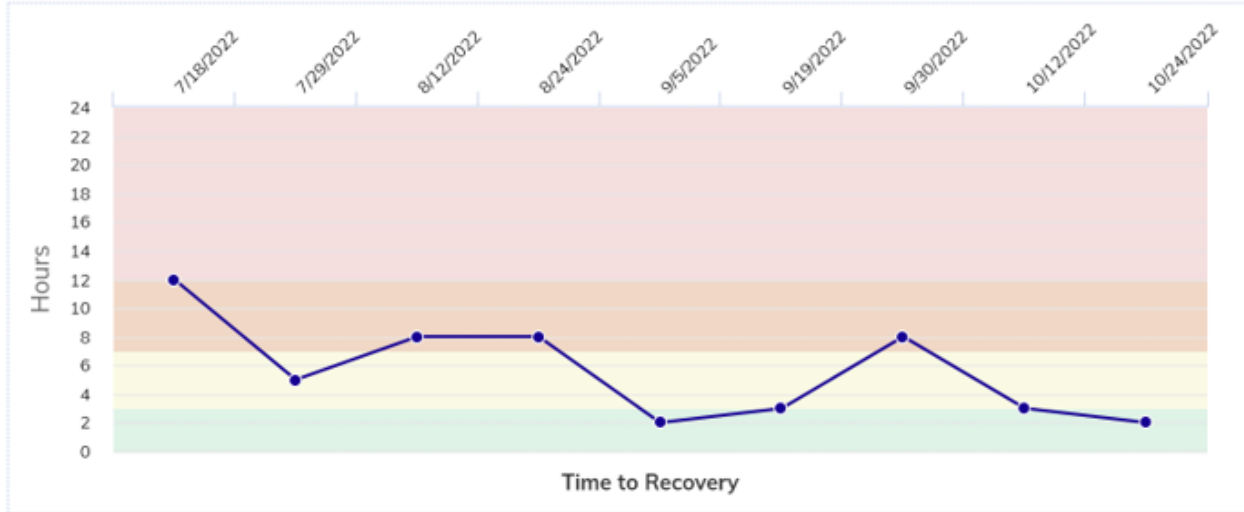
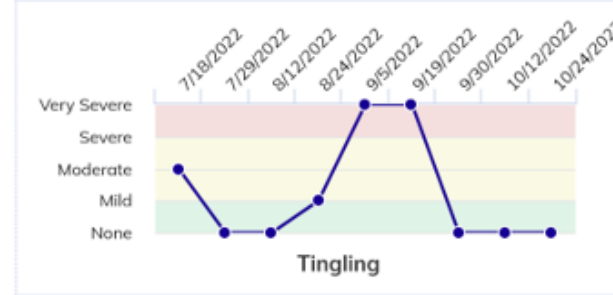
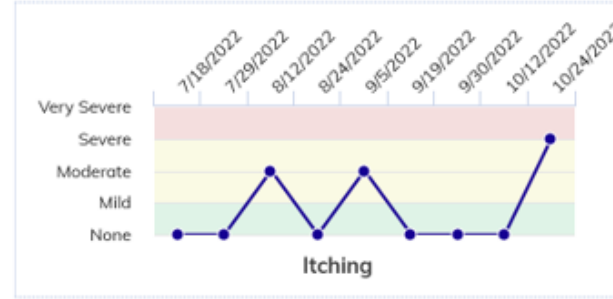
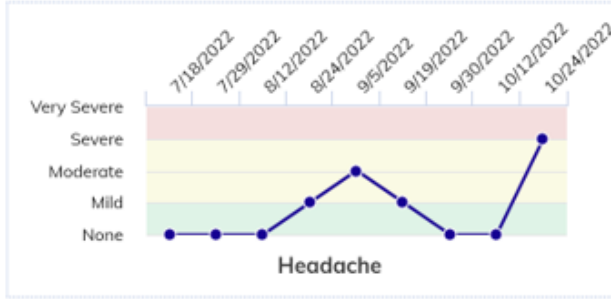
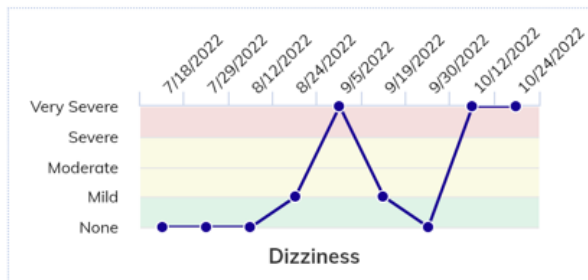
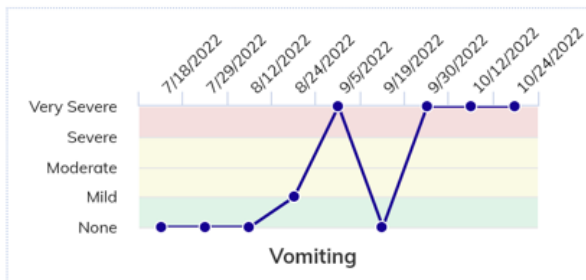
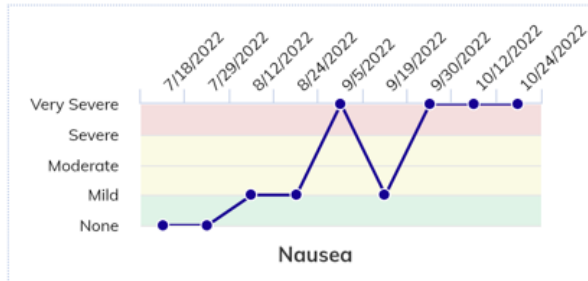
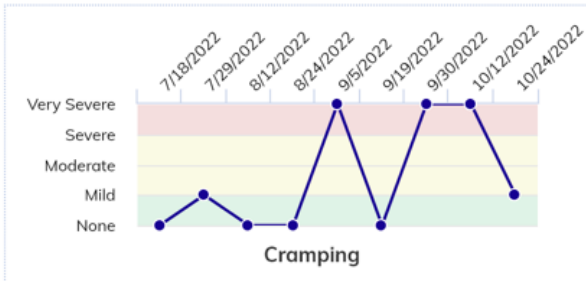
This is a SMaRRT-HD symptom report based on your patient's answers to the symptom questionnaire. The questionnaire asks patients about symptoms they had during their last hemodialysis treatment at this clinic.

Report created on: 10/26/2022

Includes dialysis treatment dates: 7/18/2022 – 10/24/2022

Symptoms during dialysis treatment on 10/24/2022, as reported by the patient on 10/26/2022:

- Alarm symptom: Chest pain (Severe), Racing heart (Severe), Shortness of Breath (Severe)
- Very severe symptoms: Dizziness, Nausea, Vomiting
- Severe symptoms: Headache, Itching, Thirst
- Recovery time: 2 hours



Patient write-ins of other symptoms:

- Mon 7/18: Diarrhea (Severe)
- Mon 7/18: Anxiety (Severe)
- Wed 8/24: Neck pain (Severe)
- Mon 9/19: No energy (Very Severe)
- Mon 10/24: Diarrhea (Severe)



Symptom Guidances for clinicians

- Overview
- Common Causes
- Clinician Assessment
- Treatment Considerations
- Resources



SMaRRT-HD™

Symptom Monitoring in Renal Replacement Therapy-Hemodialysis



TINGLING OR FEELING OF PINS & NEEDLES

GENERAL

This document is a reference tool directed to physicians/NPs/PAs and made available to other licensed caregivers (nurses, social workers, dietitians) on the multidisciplinary team at clinics participating in the SMaRRT-HD study. The tool provides physician/NP/PA assessment guidance and treatments to consider for the management of specific symptoms. This does not replace or supersede existing Fresenius Medical Care policies, algorithms, or clinical judgement. The multidisciplinary team should consult with the physician/NP/PA as needed to assess the patient and manage symptoms. The physician/NP/PA will order interventions, if indicated, for the management of symptoms.

OVERVIEW

Tingling or feelings of pins and needles are abnormal sensations that can occur anywhere in the body, but they are often felt in the fingers, hands, feet, arms, or legs. Often, but not always, they are signs of nerve dysfunction (i.e., [neuropathy](#)).

COMMON CAUSES

Potential causes of tingling or feeling of pins and needles can include

- **Dialysis-related:** AV access-induced (i.e., steal syndrome), electrolyte/mineral abnormality (e.g., Na, K, Ca, Mg, Phos), uremic polyneuropathy (from inadequate HD), uncontrolled hyperPTH
- **Comorbid conditions:** diabetes, peripheral vascular disease, nerve entrapment (e.g., carpal tunnel, positioning), vitamin deficiency (e.g., B6, B12, E, folic acid, thiamine, niacin), systemic disease (e.g., amyloid, connective tissue disorder, multiple sclerosis, paraneoplastic syndrome), liver failure, HIV, hypothyroidism, sciatica/slipped disk, infection (e.g., Lyme disease, shingles), migraine, prior trauma
- **Medications/substances:** alcohol, toxins (e.g., lead, arsenic, mercury, n-hexane), chemotherapy, antimicrobials (e.g., metronidazole, dapsone, quinolones), amiodarone, phenytoin, radiation therapy

PHYSICIAN/NP/PA ASSESSMENT

Follow up with patient and obtain additional history

- Nature of symptom, onset, severity, duration, exacerbating/relieving factors, personal and family history of neurologic disease
- Assess for concurrent symptoms (pain, itching, numbness, weakness, wasting, erectile dysfunction)
- Assess for comorbid conditions that can cause tingling or feeling of pins and needles
- Assess for medications and potential exposures

Review dialysis treatment and dietary parameters

- AV access flow rate, adequacy parameters, adherence to prescription, dialysate composition

Physical examination

- Evaluate for focal weakness, peripheral sensory deficits, reflex abnormality, balance or gait abnormality, skin changes, muscle wasting; AV access (bruit/pulsation, etc.)

Potential testing and referrals

- Electrolytes, Ca/Phos/PTH, HgbA1c, TSH, B12, thiamine CBC, Kt/V, LFTs, infection eval; consider head/back imaging, electrodiagnostic studies (e.g., EMG)
- Consider referral to primary care, neurology, palliative care, or pain specialist

TREATMENT CONSIDERATIONS

- **Treat underlying condition.** For *uremic polyneuropathy* consider longer, more frequent HD

Non-pharmacologic treatment for neuropathic symptoms

- Wear loose clothing/shoes, avoid sustained pressure to area (i.e., shift position frequently)
- Physical therapy, TENS device, acupuncture, relaxation exercises
- If from [nerve compression](#), consider steroid injections, neurolytic blocks, braces, surgery

Pharmacologic treatment for painful neuropathic symptoms as ordered by the physician/NP/PA

- **Topical:** capsaicin 0.025% ointment (compounded w/ menthol if available), lidocaine patch
- **Oral:** 1st-line agent- gabapentin (100mg TIW after HD) or pregabalin (25mg TIW after HD); if contraindicated/ineffective, consider SNRI (e.g., venlafaxine 37.5mg QD) or TCA (e.g., amitriptyline 10mg QHS). For all, start low dose, titrate slowly, and monitor for side effects. Opioids are less effective and used only in refractory cases w expert consultation.

RESOURCES

UpToDate. Overview of polyneuropathy. Gelfand, S.L., et al. *Kidney Supportive Care: Core Curriculum. Am J Kid Dis* 2020 75(5):793-806. Raouf M., et al. Pharmacotherapeutic mgmt. of neuropathic pain in ESRD. *Kid Dis* 2020 6: 157-67.

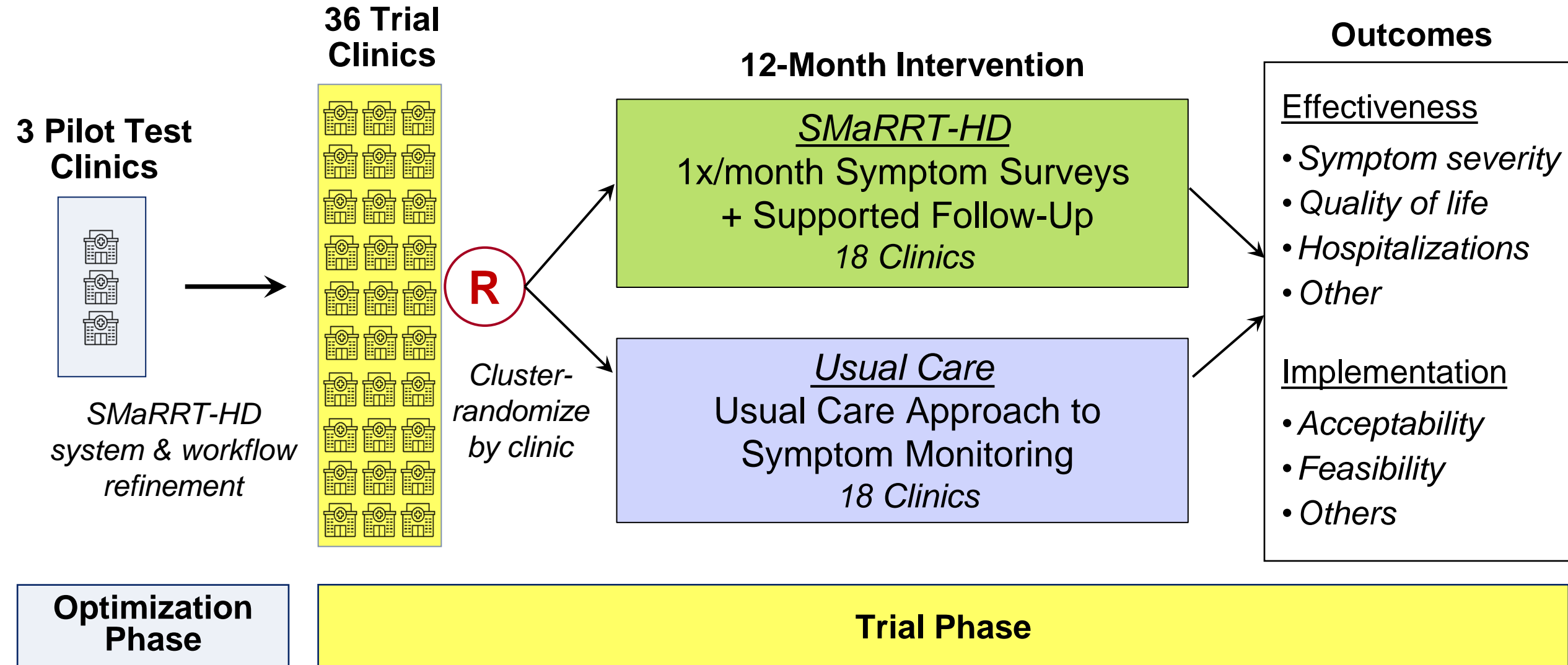
Goals for the SMaRRT-HD Study

How can dialysis care teams best monitor and improve dialysis-related symptoms?

1 Test the **effectiveness** of the SMaRRT-HD system compared to routine symptom monitoring to improve symptoms and other outcomes.

2 Evaluate the **implementation** of the SMaRRT-HD system to learn how it could best be incorporated into routine dialysis care.

Design of the SMaRRT-HD Study



The SMaRRT-HD Study is a partnership.



University of North Carolina

**Trial Coordination &
Clinic Support**

University of Pennsylvania

**Quantitative
Data Analysis**



Fresenius Medical Care

**Participating
Dialysis Clinics**



Duke University

**Implementation
Evaluation**

University of New Mexico

**Phone-collected Patient-
Reported Outcomes**



Stakeholders:



**Patients and family members
Dialysis provider organizations
Dialysis care team representatives**

**Health systems
Centers for Medicare & Medicaid Services
Professional societies**

Questions?

Contact the study team:

SMaRRT-HD@unc.edu or 1-888-804-9511

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