# A Prospective, Multi-Center, Open-Label Assessment of Efficacy and Safety of the Quanta<sup>TM</sup> Dialysis System for Home Hemodialysis

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#### Introduction

- Home hemodialysis (HHD) reduces costs while providing more flexibility and improving selected health outcomes to patients with kidney failure.
- The Quanta Dialysis System is a compact, portable and easyto-use hemodialysis (HD) device designed for a broad range of users in any setting.
- The purpose of this study is to determine non-inferiority of efficacy and safety of the Quanta Dialysis System in HHD vs facility HD.

#### Methods

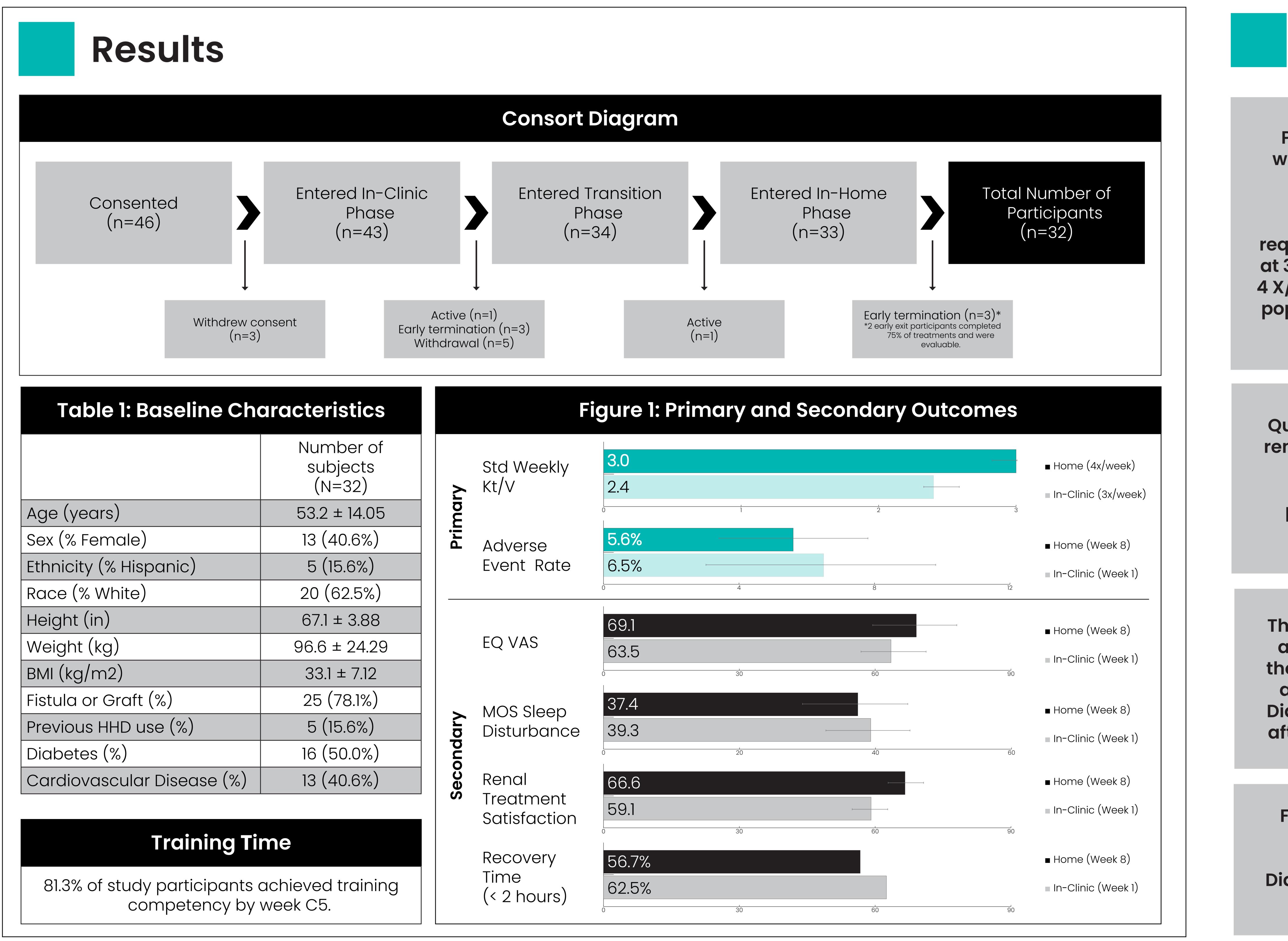
- **Design**: Prospective cohort study.
- **Population**: Adults with kidney failure receiving dialysis for >90 days and no contraindications to home hemodialysis with a care partner.
- Setting: 13 sites across the United States from November 2021 to October 2023.
- In-Clinic Phase: Participants received HD at their HHD training site 3x/week for 4-8 weeks while they and their caregivers trained to use the Quanta Dialysis System at home.
- In-Home Phase: Once approved by a nephrology care team, study participants performed supervised HHD during a transition week, then performed HHD 4x/week at home for 8 weeks.
- Primary Outcomes: Dialysis adequacy (mean standardized weekly Kt/V) and composite of adverse events.
- Secondary Outcomes: Time to recover, quality of life, sleep quality, renal treatment satisfaction.

### Limitations

- This study could not be conducted as a randomized cross-over trial due to training requirement.
- Heterogeneity observed in the results across sites and subgroups.
- Fourteen patients withdrew from the study early; however, the majority of withdrawals were unrelated to the device and procedure

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The SC+ Hemodialysis System\* is FDA 510(k)-cleared (K222067) for use in patients with acute and/or chronic care facility. Treatments must be administered under physician's prescription, by a trained person who is competent in the use of the device. Treatment types available: Intermittent Renal Replacement Therapy (PIRRT), Isolated Ultrafiltration including Slow Continuous Ultrafiltration (SCUF) and Continuous Venovenous Hemodialysis (CVVHD). \*SC+ is now known as the Quanta Dialysis System. © 2023 Quanta Dialysis Technologies ® Ltd and/or its subsidiaries or affiliates ("QTD"). All rights reserved. The Quanta Dialysis Technologies ® Ltd and/or its subsidiaries or affiliates ("QTD"). limitation and Quanta<sup>™</sup> logos, trade dress, or other countries. Any trademarks or service marks references herein are the property of their respective owners. NPC-55

## Conclusions

Performing self-care HHD with a care partner with the Quanta Dialysis System provides well above the weekly standard Kt/V required for dialysis adequacy at 3x/week in facility (2.4) and 4 X/week in the home (3.0) in a population exceeding a mean weight of 210 lbs.

Quality of life, sleep quality, renal treatment satisfaction and time to recover improved in the home phase compared to the clinic phase.

The majority of participants achieved competency by the 5th week of training and are still using the Quanta Dialysis System up to 1 year after completing the study.

**Future direction includes** assessing technique survival of the Quanta Dialysis System in the home setting.

