The Community Health Workers and Mobile Health for Emerging Adults Transitioning Sickle Cell Disease Care (COMETS) Trial: Protocol for a Randomized Controlled Trial

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Background
Transitioning from pediatric to adult sickle cell disease (SCD) care is challenging for emerging adults (aged 17-25 years). This period is marked by a 7-fold increase in mortality rates and has the highest rates of hospitalizations, emergency room visits, and hospital readmissions compared with children living with SCD. These challenges are exacerbated by fragmented care coordination, difficulty navigating adult health care systems, and increased self-management responsibilities.

Objective
This study aims to compare the effectiveness of 2 interventions designed to support emerging adults living with SCD during this transition: a mobile health (mHealth) app and community health worker (CHW) support to standard care.

Methods
The Community Health Workers and Mobile Health for Emerging Adults Transitioning Sickle Cell Disease Care (COMETS) trial is an ongoing multicenter, 3-arm, open-label randomized controlled trial; 375 emerging adults (aged 17-25 years) are being enrolled and randomized 1:1:1 to (1) a 6-month CHW intervention focused on self-management skills, symptom tracking, care coordination, and transition planning; (2) a 6-month mHealth self-management program (enhanced iManage application) with tailored SMS text messaging (THRIVE [Texting Health-Related Resources to Inform, Motivate, and Engage] 2.0); or (3) enhanced usual care (control). Participants are followed for 18 months. The primary outcome is the change in self-reported health-related quality of life assessed using the PedsQL SCD module. Secondary outcomes include acute care use (hospitalizations and emergency department visits), patient activation, self-management behavior, and successful transfer to adult hematology care.

Results
The institutional review board at Children's Hospital of Philadelphia approved this study in June 2018. Recruitment began in January 2019 and ended in December 2022; we completed data collection in November 2024. We have enrolled a total of 405 participants.

Conclusions
This trial addresses a critical gap in transition intervention research for young adults with SCD. It will provide evidence on the comparative effectiveness of 2 promising interventions (CHW and mHealth) and inform the development of scalable and sustainable transition support programs. Findings will have implications for improving health-related quality of life, reducing acute care use, and promoting successful transition to adult-centered SCD care for this vulnerable population.

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