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*Review Article*

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# Evaluating the Efficacy of AI-Driven Real-Time Monitoring and Intervention for Managing Body Fluid Imbalances in Sickle Cell Disease in Sub-Saharan Africa: A Randomized Control Trial

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**ABSTRACT**

This study will test a new AI-powered system designed to help manage sickle cell disease (SCD) in Sub-Saharan Africa. SCD is a devastating genetic disorder, and dehydration is a major trigger for painful and dangerous complications called vaso-occlusive crises (VOCs). Current monitoring methods are not effective in regions with limited healthcare access.

The main goal is to see if the AI system reduces the number of VOCs requiring medical care over 24 months. Secondary goals include measuring its impact on other complications, quality of life, healthcare costs, and how easy the system is to use.

The research will use a randomized controlled trial, the gold standard for testing medical interventions. It will involve 600 participants aged 12-45 from Nigeria, Ghana, and Tanzania. They will be randomly split into two groups.

The intervention group will use a special kit that includes wearable sensors (like a smartwatch) to track heart rate and activity, a smart water bottle that measures how much they drink, and a smartphone app. An AI algorithm will analyze this data in real-time to provide personalized hydration alerts. The control group will receive standard education on hydration and use a traditional water bottle and diary.

The study is designed for real-world conditions in Africa, with a focus on community input and a system that works even with poor internet. Strengths include its rigorous design and multi-country approach. A key limitation is that participants will know which group they are in. If successful, this research could transform SCD care from reactive to proactive, saving lives and providing a model for managing other diseases in low-resource settings.

## Introduction

Sickle Cell Disease (SCD) is a devastating genetic disorder with a disproportionate impact on Sub-Saharan Africa. The region accounts for over 75% of the estimated 300,000-400,000 global annual SCD births, with a tragic mortality rate where 70-80% of affected children do not survive to their fifth birthday. The disease is characterized by the production of abnormal hemoglobin S, which polymerizes under low oxygen conditions, causing red blood cells to sickle. This leads to chronic hemolysis, painful vaso-occlusive crises (VOCs), widespread organ damage, and premature death [1].

A critical, modifiable factor in this cycle is body fluid imbalance. Dehydration significantly increases blood viscosity, directly potentiating the sickling process and the frequency and severity of VOCs. The central research problem is the profound

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inadequacy of current healthcare approaches to monitor and manage this fluid imbalance in the resource-constrained settings of Sub-Saharan Africa. Traditional methods, which rely on periodic clinic visits and patient self-monitoring, are ill-suited to regions with sporadic healthcare access, limited infrastructure, and low health literacy [2].

While Artificial Intelligence (AI) and wearable technologies show promise in chronic disease management in high-income countries, they are largely unsuitable for Sub-Saharan Africa. Current iterations depend on stable internet connectivity, advanced healthcare infrastructure, and centralized data systems resources often unavailable in this context. Furthermore, they frequently fail to account for the region's unique socio-environmental challenges, including fluctuating climatic conditions, intermittent power supplies, cultural barriers to technology adoption, and varying literacy levels [3].

The significance of this research lies in its potential to bridge these critical gaps by developing and rigorously evaluating a context-specific, AI-driven monitoring system. By leveraging adaptive machine learning and cost-effective wearable sensors, the proposed system aims to provide real-time, personalized interventions to prevent life-threatening complications like VOCs and Acute Chest Syndrome (ACS). This represents a paradigm shift from reactive crisis management to proactive, preventative care. If successful, it could transform SCD care delivery for millions of underserved individuals and establish a replicable framework for implementing advanced health technologies in challenging environments [4-6].

**Study Objectives and Hypotheses**

The study establishes clear, measurable objectives to evaluate the AI-driven system's efficacy.

**Primary Objective**

To evaluate the effectiveness of the AI-based intervention for the real-time monitoring and management of body fluid imbalances, compared to standard care alone.

**Secondary Objectives**

- Comparing the frequency of SCD-related vaso-occlusive crises (VOCs) between the intervention and control groups.
- Assessing the impact on the incidence of acute chest syndrome (ACS).
- Measuring cost-effectiveness and patterns of healthcare utilization (e.g., hospitalizations, emergency visits).
- Evaluating improvements in quality of life and reduction in inter-crisis pain.
- Determining system usability and acceptability among both patients and healthcare providers.

**Research Hypotheses**

Based on these objectives, the study tests four central hypotheses

1. The intervention group will experience a statistically significant lower rate of VOCs requiring medical attention over 24 months compared to the control group.
2. The intervention group will demonstrate a lower incidence of ACS and other fluid-imbalance-related complications.
3. The intervention group will report significantly better quality of life and lower inter-crisis pain scores on validated patient-reported outcome (PRO) measures.
4. The AI-driven system will be deemed highly usable and acceptable by over 80% of users (patients and providers), indicating strong potential for sustained implementation.

**Methodology Overview**

**Study Design**

The research employs a Randomized Controlled Trial (RCT) design, the gold standard for establishing causal relationships between an intervention and outcomes. It uses a parallel-group structure with 1:1 allocation to intervention and control groups. To enhance methodological rigor, the study implements a single-blind procedure where outcome assessors and data analysts are blinded to group assignments, minimizing measurement bias. However, complete participant blinding is not feasible due to the nature of the technological intervention [7,8].

Crucially, the trial adopts a pragmatic approach, evaluating the intervention's effectiveness in "real-world" conditions within Sub-Saharan Africa's healthcare environment, rather than in an idealized controlled setting. This reflects the researchers' intention to assess feasibility and performance amid actual constraints like infrastructure limitations and variable patient adherence [9-14].

**Study Duration and Timeline**

The study spans 24 months per participant, structured into distinct phases:

- Run-in Phase (2 weeks): Initial recruitment, baseline assessments, and system orientation for the intervention group.
- Active Intervention Phase (12 months): The core period where the AI-driven system is actively used, with continuous data collection and monitoring.
- Post-Intervention Follow-up (12 months): An observation period to assess sustained effects, long-term adherence, and potential delayed outcomes. This extended timeline allows for the assessment of seasonal variations in SCD complications.

**Participant Recruitment and Sampling**

**Eligibility Criteria**

Precise criteria were established to define a homogeneous yet representative study population.

- **Inclusion Criteria:** Confirmed SCD diagnosis (HbSS or HbSβ⁰-thalassemia genotype); age 12-45 years; history of ≥2 VOCs requiring medical attention in the previous year; access to a compatible smartphone; residence within 50km of a study clinic; and willingness to provide informed consent.
- **Exclusion Criteria:** Severe chronic comorbidities affecting fluid balance (e.g., advanced kidney disease); pregnancy; cognitive impairment; concurrent participation in another trial; and inability to understand the study languages.

**Sampling Technique and Sample Size**

The study employs a stratified random sampling technique within a consecutive enrollment framework. Participants are stratified by:

a. Geographic study center (Nigeria, Ghana, Tanzania)
b. Age group (12-17 years vs. 18-45 years)
c. Frequency of prior VOCs (2-3 in past year vs. ≥4 in past year)

The sample size calculation, based on the primary outcome of VOC rate reduction, determined that 600 participants (300 per group) are required. This provides 90% power to detect a 30% reduction in VOC rate, accounting for an anticipated 15% dropout rate. The sample is distributed equally across the three participating countries.

**Randomization Procedure**

A computer-generated randomization sequence is created by an independent statistician using block randomization within each stratification cell. After informed consent and baseline assessments, participants are formally enrolled and assigned to their group via a centralized electronic system, ensuring allocation concealment and minimizing selection bias.

**Table 1: Sample Size Distribution Across Participating Countries**

| Country | Intervention Group | Control Group | Total |
|---|---|---|---|
| Nigeria | 100 | 100 | 200 |
| Ghana | 100 | 100 | 200 |
| Tanzania | 100 | 100 | 200 |
| Total | 300 | 300 | 600 |

**Intervention Protocol**

**AI-Driven Intervention Components**

This is the novel; multi-component system being tested. Participants in this group receive the AI-driven system plus standard care.

The intervention group receives a comprehensive AI-driven system in addition to standard care. Its integrated components are:

- **Wearable Sensors:** Smartwatches or bracelets, Belt, bra, or Chatbot for Hospitals for hospitalized patients to monitor physiological data (heart rate, hydration levels, activity levels) to check for signs of hypotension, Tachycardia.
- **Smart Water Bottles:** Bluetooth-connected containers that automatically measure fluid intake.
- **Smartphone Application:** A customized mobile platform that integrates sensor data, self-reported symptoms, and environmental information (e.g., local temperature).
- **AI Algorithm:** The core innovation a predefined, adaptive machine learning system that analyzes integrated data in real-time to generate personalized hydration alerts and behavioral nudges. It is specifically designed to function with intermittent connectivity.
- **Clinical Dashboard:** A web-based interface for healthcare providers to monitor patient status and receive automated alerts for early intervention.
- **Personalized Hydration Alerts:** Notifications to drink more water.
- **Behavioral Nudges:** Context-aware suggestions to help manage hydration.
- **Feature:** The system is specifically designed for resource-limited settings in Sub-Saharan Africa, with capabilities to function under intermittent internet connectivity.

**The Control Intervention Group Protocol**

This group receives Enhanced Standard Care to ensure a fair comparison and control for the attention participants in the intervention group receive.

**Components:**

- **Standard SCD Education:** Patients receive the usual education about the importance of hydration and how to manage it, consistent with local standards of care.
- **Traditional Water Bottle and Paper-Based Hydration Diary:** Instead of smart technology, they are given a regular water bottle and a paper diary to manually record their daily fluid intake.
- **Regular Clinical Assessments:** They continue to receive routine medical care and

**Summary Table of Interventions**

| Feature | AI-Driven Intervention Group | Control Group (Enhanced Standard Care) |
|---|---|---|
| Core Approach | Proactive, technology-enabled, real-time monitoring and feedback. | Reactive, traditional self-management with education. |
| Monitoring | Continuous via wearable sensors and smart bottles. | Manual self-reporting via a paper diary. |
| Feedback | Real-time, personalized alerts and nudges from an AI algorithm. | General education and advice during clinic visits. |
| Technology | Wearables, smart bottles, smartphone app, clinical dashboard. | Paper diary, traditional water bottle. |
| Healthcare Provider Role | Remote monitoring via dashboard with automated alerts. | Standard in-clinic consultations based on patient reporting. |

In essence, the study is evaluating the added benefit of the AI-driven real-time monitoring and intervention system over and above a robust version of the current standard of care.

**The AI-Driven Intervention (For the Intervention Group)**

This is the novel; multi-component system being tested. Participants in this group receive the AI-driven system plus standard care.

**Components:**

- **Wearable Sensors:** Smartwatches or bracelets that continuously monitor physiological data like heart rate and activity levels. Specialized sensors are used to track hydration status.
- **Smart Water Bottles:** Bluetooth-connected bottles that automatically measure and record a patient's fluid intake.
- **Smartphone Application:** A custom mobile app that integrates data from the sensors, smart bottle, and patient self-reports (e.g., symptoms, urine color). It also incorporates environmental data like local temperature.
- **AI Algorithm:** The core of the intervention. This machine learning system analyzes all the integrated data in real-time

to identify patterns predictive of fluid imbalance. It then generates:

- **Personalized Hydration Alerts:** Notifications to drink more water.
- **Behavioral Nudges:** Context-aware suggestions to help manage hydration.

- **Clinical Dashboard:** A web-based interface for healthcare providers to monitor their patients' status remotely and receive automated alerts for early intervention if a patient's data indicates a high risk.
- **Feature:** The system is specifically designed for resource-limited settings in Sub-Saharan Africa, with capabilities to function under intermittent internet connectivity.

**Implementation Framework**

The intervention follows a structured plan with multiple work packages (WPs) to ensure systematic rollout and evaluation:

- **WP1:** Community Co-Design & AI Platform Setup: Establishing Community Advisory Boards, co-designing user interfaces, and training local staff.
- **WP2:** Randomized Controlled Trial: Covers all trial operations from screening to data collection.
- **WP3:** Qualitative Evaluation & Implementation Science: Involves in-depth interviews and focus groups to understand user experience and develop frameworks for scaling.

**Data Collection and Management**

**Primary Outcome Measure**

The primary endpoint is the rate of acute vaso-occlusive crises (VOCs) per person-year, with a VOC defined as an acute pain episode requiring medical attention. This is a clinically meaningful and regulatory-recognized surrogate for clinical benefit in SCD. Data is collected through medical record review, patient self-reporting via the app, and healthcare provider confirmation.

**Secondary Outcome Measures**

Secondary endpoints provide a comprehensive assessment:

- **Incidence of Acute Chest Syndrome (ACS):** Confirmed radiographically and clinically.
- **Quality of Life:** Measured using validated PROs, specifically the Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-ME) and Pain Frequency and Severity scales.
- **Healthcare Utilization:** Hospitalization rates, emergency department visits, and length of stay.
- **Cost-effectiveness:** Direct medical costs and incremental cost-effectiveness ratios.
- **System Usability and Acceptability:** Measured via standardized scales (e.g., System Usability Scale) and qualitative feedback.

**Data Collection Schedule**

Data is collected at predetermined intervals to balance comprehensiveness with participant burden:

- **Baseline:** Comprehensive demographic, clinical, and laboratory data.
- **Monthly:** PRO measures, healthcare utilization, and adherence metrics.
- **Quarterly:** Complete physical examination and laboratory studies.
- **Continuous:** Real-time sensor data and AI system interactions.
- **Study Exit:** Final assessment repeating baseline measures.

**Statistical Analysis Plan**

**Primary Analysis**

The primary analysis follows the intention-to-treat (ITT) principle, including all randomized participants in their original groups regardless of adherence. The rate of VOCs will be compared using negative binomial regression (suitable for count data), which will estimate the incidence rate ratio (IRR) with 95% confidence intervals. The model will adjust for the stratification variables (study center, age group, baseline VOC frequency) to enhance precision.

**Secondary and Subgroup Analyses**

- Secondary continuous outcomes (e.g., quality of life scores) will be analyzed using linear mixed models to account for repeated measurements over time.
- Binary outcomes (e.g., ACS incidence) will be compared using generalized estimating equations.
- Pre-specified subgroup analyses will examine whether treatment effects vary by age, gender, disease severity, country, and level of technology adherence.

**Missing Data Handling**

Proactive measures (reminder systems, incentives) will minimize missing data. For the primary analysis, multiple imputation techniques will be employed, with sensitivity analyses to assess the hugeness of the findings.

**Ethical Considerations**

**Ethical Approval and Informed Consent**

The study protocol requires and receives approval from institutional review boards (IRBs) or ethics committees in all participating countries and institutions. The informed consent process is adapted for diverse literacy levels, using simplified forms, visual aids, and verbal verification of understanding. For adolescents, dual consent from parents/guardians and assent from the participants themselves is obtained.

**Data Privacy and Security**

Given the continuous collection of sensitive physiological and health data, robust data protection measures are implemented, aligned with international standards (e.g., GDPR) and local regulations. These include data encryption, secure cloud infrastructure with access controls, data anonymization for analysis, and clear data retention policies.

**Monitoring and Adverse Event Reporting**

An independent Data Safety Monitoring Board (DSMB) provides oversight, reviewing data for safety concerns and protocol deviations. Adverse events are documented and reported according to severity and relationship to the intervention, with special attention to risks like skin irritation from wearables or data privacy issues.

**Methodological Strengths and Limitations**

**Strengths**

- **Pragmatic Design:** Enhances the generalized findings to real-world conditions in Sub-Saharan Africa.

- **Multi-Country Approach:** Increases geographic representation and external validity.
- **Comprehensive Outcome Assessment:** The combination of clinical events, PROs, and economic measures provides a holistic evaluation of the intervention's value.
- **Community Engagement:** The co-design process enhances cultural appropriateness and potential for long-term sustainability.
- **Rigorous Randomization:** Stratified random allocation minimizes selection bias and ensures balance on key prognostic factors.

**Limitations**

- **Inability to Blind Participants:** Performance bias is possible as participants know their group assignment.
- **Technology Dependency:** System performance is vulnerable to technical failures in multiple components (sensors, apps, connectivity).
- **Generalizability Constraints:** Excluding younger children and older adults' limits understanding of the intervention's effect across the full SCD age spectrum.
- **Resource Intensity:** The comprehensive intervention and evaluation require substantial resources, which could affect its scalability.
- **Short-Term Follow-up:** A 24-month period may be insufficient to capture long-term outcomes, sustainability of effects, and rare adverse events.

**Conclusion**

This research methodology outlines a comprehensive and rigorous approach to evaluating an innovative, AI-driven solution for a critical problem in SCD Crisis curative and management in Sub-Saharan Africa. By combining the gold-standard RCT design with pragmatic implementation considerations and deep community engagement, the study is positioned to generate valuable evidence about both the efficacy and real-world feasibility of the intervention.

The meticulous attention to cultural adaptation, resource constraints, and healthcare system integration distinguishes this research from previous technology-focused initiatives that have struggled in low-resource settings. This approach has the potential to establish a new paradigm not only for SCD care but also for managing other chronic diseases in challenging environments. The findings from this study will be crucial in addressing the significant burden of Sickle Cell Disease in a region where innovative and context-appropriate solutions are urgently needed to reduce mortality and improve the quality of life for millions.

**Participant Eligibility, Recruitment, and Flow Chart.**

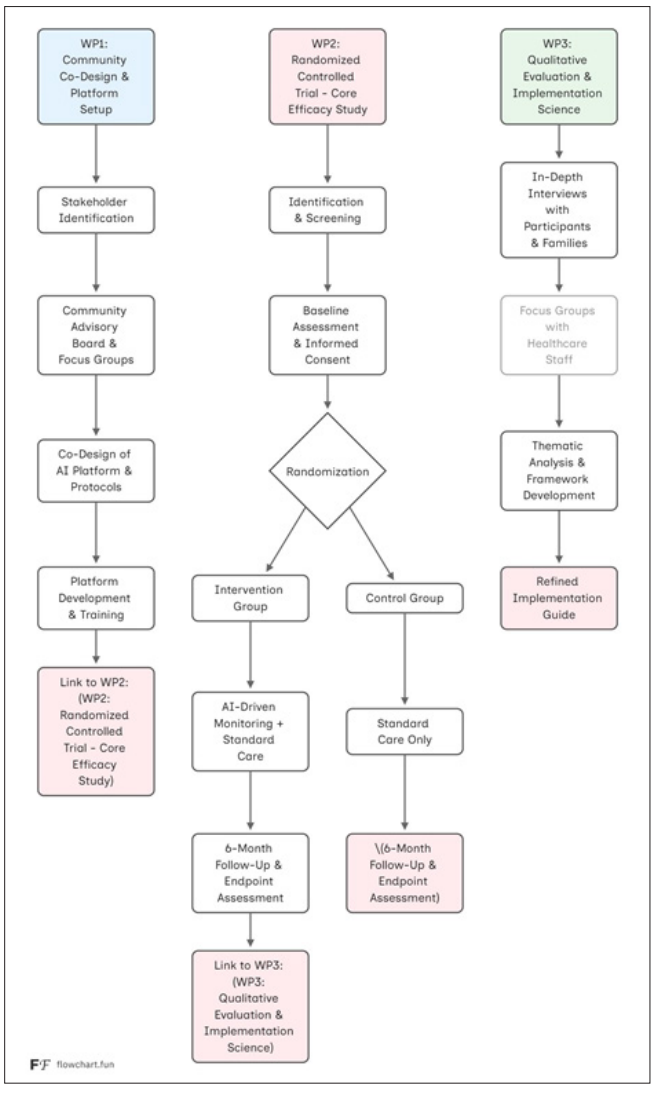

**Table 2: Participant Eligibility, Recruitment, and Flow**

| Category | Details | |
|---|---|---|
| **Study Population** | Individuals diagnosed with Sickle Cell Disease (SCD) in Sub-Saharan Africa. | |
| **Target Sample Size** | 600 participants | |
| **Recruitment Settings** | Tertiary care hospitals and specialized sickle cell clinics in urban centers across Nigeria, Ghana, and Tanzania. | |
| **Recruitment Strategy** | Consecutive enrollment of eligible patients attending clinics during the enrollment period, supported by community outreach and local media campaigns. | |
| **Eligibility Criteria** | **Inclusion Criteria** | **Exclusion Criteria** |
| **Diagnosis** | Confirmed diagnosis of SCD (HbSS or HbSβ⁰-thalassemia genotype). | Severe chronic comorbidities that independently dictate fluid management (e.g., advanced renal failure on dialysis, severe chronic heart failure). |
| **Age** | 12 to 45 years old. | |
| **Disease History** | History of at least two Vaso-Occlusive Crises (VOCs) requiring medical attention in the previous 24 months. | Pregnancy or planning pregnancy during the study period. |
| **Technology & Access** | Ownership of, or reliable access to, a compatible smartphone. Resident within a reasonable distance (<50 km) of a participating study clinic. | Cognitive impairment or severe psychiatric illness that precludes informed consent or protocol adherence. |
| **Consent** | Willing and able to provide informed consent (and assent for minors as per national guidelines). | Concurrent participation in another interventional clinical trial. Inability to understand the primary language(s) of the study. |
| **Group Allocation & Intervention** | **Intervention Group (n=300)** | **Control Group (n=300)** |
| **Allocation** | Random assignment via a computer-generated sequence with block randomization within strata (Country, Age, VOC history). | |
| **Core Protocol** | AI-Driven System + Standard Care | Enhanced Standard Care |
| **Components** | 1. Wearable Sensors (e.g., smart bracelet/watch) to monitor physiology (heart rate, activity).<br>2. Smart Water Bottle to track fluid intake.<br>3. Smartphone App with an AI algorithm for real-time, personalized hydration alerts and nudges.<br>4. Clinical Dashboard for healthcare provider alerts. | 1. Standard SCD Education on hydration importance.<br>2. Traditional Water Bottle and a Paper-Based Hydration Diary for self-monitoring.<br>3. Routine clinical care and management of acute events. |

**Table 3: Showing Total Study Duration per Participant 24 Months**

| Stratification Variables | Description |
|---|---|
| Study Center | To account for country-specific and clinic-specific variations in care and environment (Nigeria, Ghana, Tanzania). |
| Age Group | To ensure balance between adolescents (12-17 years) and adults (18-45 years). |
| Prior VOC Frequency | To balance disease severity across groups (2-3 VOCs in past year vs. ≥4 VOCs in past year). |

This table provides a comprehensive overview of who the participants will be, how they will be selected and assigned, what they will receive during the trial, and the timeline for their involvement.

**Table 4: Showing Data Collection Timeline and Methods**

| Timepoint | Clinical Data | PRO Measures | Sensor Data | Healthcare Utilization |
|---|---|---|---|---|
| Baseline | ✓ | ✓ | - | ✓ |
| Monthly | - | ✓ | Continuous | ✓ |
| Quarterly | ✓ | ✓ | - | - |
| Adverse Events | As occurred | - | - | As occurred |
| Study Exit | ✓ | ✓ | - | ✓ |

**Table 5: Showing Data Extraction Plan for the RCT**

| Data Category | Specific Variables / Measures | Method of Extraction/ Instrument | Source | Frequency/Timing |
|---|---|---|---|---|
| **I. Baseline & Demographic Data** | | | | |
| | Age, Gender, Country, Location (Urban/Rural) | Standardized Case Report Form (CRF) | Patient Interview | Baseline Only |
| | Socioeconomic Status (Education, Occupation) | Simplified Wealth Index Questionnaire | Patient Interview | Baseline Only |
| | SCD Genotype (HbSS, HbSβ⁰, etc.) | Medical Record Abstraction | Hospital/Lab Records | Baseline Only |
| | Medical & Medication History | Medical Record Abstraction & Patient Interview | Hospital Records & CRF | Baseline Only |
| **II. Primary Clinical Outcome** | | | | |
| | Rate of Acute Vaso-Occlusive Crises (VOCs) | - Medical record verification<br>- Patient self-report via app<br>- Healthcare provider confirmation | Hospital Records, App Database, Clinician CRF | Continuous (as occurred), verified monthly |
| **III. Secondary Clinical Outcomes** | | | | |
| | Incidence of Acute Chest Syndrome (ACS) | Radiographic evidence + clinical diagnosis (as per predefined criteria) | Hospital Records, Clinician CRF | Continuous (as occurred), verified monthly |
| | Other Complications (e.g., Stroke, Priapism) | Medical record abstraction using predefined codes | Hospital Records, Clinician CRF | Continuous (as occurred), verified monthly |
| | Mortality | Medical record abstraction and family report | Hospital Records, Clinician CRF | Continuous |
| **IV. Patient-Reported Outcomes (PROs)** | | | | |
| | Pain Frequency and Severity | Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) | Smartphone App & Follow-up Interviews | Daily (app), Monthly (interview verification) |
| | Health-Related Quality of Life | Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-Me) | Tablet-based/Paper Questionnaire | Baseline, 6 Months, 12 Months,24 months |
| | Fatigue, Sleep Quality, Emotional Impact | Relevant domains of ASCQ-Me or other validated PROMs | Tablet-based/Paper Questionnaire | Baseline, 6 Months, 12 Months, 24 months |
| **V. Physiological & Sensor Data** | | | | |
| | Hydration Status Biomarkers (if available) | Hematocrit, Creatinine | Lab Results from Routine Care | As available during standard care visits |
| | Heart Rate, Activity Level | Continuous data stream | Wearable Sensors (e.g., Smart Bracelet) | Continuous (real-time) |
| | Fluid Intake Volume | Automated volume tracking | Smart Water Bottle | Continuous (real-time) |

| | | | | |
|---|---|---|---|---|
| | Self-reported Urine Color, Thirst | Patient input | Smartphone App | Daily |
| **VI. Healthcare Utilization & Economic Data** | | | | |
| | Hospitalization Rates & Length of Stay | Medical record abstraction | Hospital Records & CRF | Monthly |
| | Emergency Department Visits | Medical record abstraction | Hospital Records & CRF | Monthly |
| | Outpatient/Clinic Visits | Medical record abstraction & self-report | Hospital Records & CRF | Monthly |
| | Medication Use (e.g., Hydroxyurea, Opioids) | Pharmacy records & self-report | Hospital/Pharmacy Records & CRF | Monthly |
| | Direct Medical Costs | Cost data associated with hospital stays, medications, and procedures | Hospital Billing/Admin Records | End of Study |
| **VII. Intervention-Specific & Feasibility Data** | | | | |
| | System Usability | System Usability Scale (SUS) | Questionnaire | 6 Months, 12 Months,24month |
| | Technology Acceptability | Technology Acceptance Model (TAM) questionnaire or structured interviews | Questionnaire & Qualitative Interviews | 12 Months |
| | Adherence Metrics | - Wearable sensor wear-time<br>- App engagement (logins, data entries)<br>- Smart bottle usage | Backend System Analytics | Continuous (aggregated weekly/monthly) |
| | AI Algorithm Performance | | Backend System Analytics | Continuous |
| | Barriers & Facilitators to Use | | In-depth Interviews & Focus Groups (with a sub-sample) | 12 Months |

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