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POSTER ABSTRACTS

114.SICKLE CELL DISEASE, SICKLE CELL TRAIT AND OTHER HEMOGLOBINOPATHIES, EXCLUDING THALASSEMIAS: CLINICAL AND EPIDEMIOLOGICAL

Habit Efficacy Trial: A Multi-Site Randomized Controlled Trial of Community Health Worker Support to Increase Hydroxyurea Adherence of Youth with Sickle Cell Disease

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Introduction: Despite disease-modifying effects of hydroxyurea (HU) on sickle cell disease (SCD), poor adherence among affected youth commonly impedes treatment impact. The HABIT multi-site randomized controlled efficacy trial aimed to increase HU adherence.
Methods: Youth with SCD ages 10-18 years with impaired adherence were identified through laboratory evidence, primarily flagging levels of treatment-induced fetal hemoglobin (HbF). Eligible youth were enrolled as dyads with their primary caregivers for one year. We tested a 6-month phase of semi-structured supportive, multi-dimensional dyad intervention led by community health workers (CHW) with 4-5 visits addressing information, social issues/referrals, barriers, habit formation using goal-setting and cues, augmented by daily tailored automated text message reminders, compared to standard care. This phase was followed by a 6-month sustainability phase (months 7-12) of observation and, for the intervention group, 1 CHW booster visit. Primary intervention outcomes were 1) HbF levels compared to enrollment; and 2) proportion of days covered (PDC) for HU versus the pre-trial year. The secondary outcome was sustainability of these changes up to month 12.
Results: Starting in 2020, the COVID-19 pandemic disrupted enrollment and clinic-based procedures. The trial enrolled 50 dyads, missing target enrollment. Compared to enrollment levels, both HbF level and PDC significantly improved within the intervention group at month 6 (p=. **03** and . **01**, respectfully), with parallel increased MCV (p=.05). Increased HbF did not reach signifance compared to controls (p=.07). No significant within- or between-group differences were found at month 12.
Conclusions: Within-group results suggest that our CHW-based dyad intervention with text message reminders improved HU adherence at 6 months but there were no between-group differences. Effects did not endure through the subsequent 6-month sustainability phase. These findings suggest that improved HU adherence for youth with SCD though our community-based, multi-modal support for youth-caregiver dyads temporarily improved usage. Durability of impact on adherence may require integrating CHW-led support and text reminders into clinical care.

Disclosures Green: *AddMedica:* Other: Donated study drug for an NIH-funded clinical trial. **Manwani:** *Novartis, Pfizer, Novo Nordisk, Editas, GBT:* Consultancy. **Aygun:** *GBT:* Membership on an entity's Board of Directors or advisory committees; *bluebird bio:* Membership on an entity's Board of Directors or advisory committees, Research Funding; *Pfizer:* Membership on an entity's Board of Directors or advisory committees, Research Funding. **Smith-Whitley:** *Pfizer, Inc.:* Current Employment.

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Table 1. Sample characteristics and primary outcome of youth at enrollment, by study group. Mean values and standard deviations (SD) or numbers (percentages) are shown. Months 6 and 12 completed the intervention and sustainability phases, respectively. Primary outcomes: HbF change and PDC (proportion of days covered (PDC) – not shown) at month 6. No significant between-group differences were seen.

	Intervention Group N=24	Control Group N=26	p-value
Age (years) (mean, SD)	14.1±1.9	13.1±1.7	0.051
Youth sex (% female; N)	12 (50.0%)	11± (42.3%)	0.59
Black race (N)	21 (87.5%)	20 (76.9%)	0.33
Ethnicity (Latino/a) (N)	3 (12.5%)	5 (19.2%)	0.52
Born in United States (N)	20 (83.3%)	18 (69.2%)	0.24
Grade level (mean, SD)	8.3±1.8	7.4±2.1	0.11
Age started HU (in years) (mean, SD)	8.3±3.2	7.9±2.4	0.61
Age of personal best (in years) (mean, SD)	10.9±2.5	10.0±2.5	0.23
No additional chronic conditions (N)	12 (50.0%)	13 (50.0%)	1.00
Number of daily medications beyond hydroxyurea (mean, SD)	2.7±0.9	2.7±0.8	0.84
Participants taking any medications ≥2 times daily (N)	15 (62.5%)	10 (38.5%)	0.09
Number of ED visits during the prior year for SCD (mean, SD)*	1.0±1.5	0.8±1.4	0.64
Participants with any ED visits during the prior year (N)	11± (45.8%)	10 (40.0%)	0.68
Number of hospitalizations during prior year (mean, SD)	1.0±1.9	1.0±1.7	0.94
Participants with any hospitalizations in pre-trial year (N)	11± (45.8%)	11 (44.0%)	0.90
HU dose at personal based HbF (mean, SD)	25.1±4.0	23.6±4.0	0.20
HU dose at enrollment (mean, SD)	26.6±4.3	25.7±4.7	0.50
Social Vulnerability Index (mean, SD)	0.84±0.19		
Historical Personal Best HbF (mean, SD)	22.9±11.3	19.2±7.4	0.18
HbF at Enrollment (month 0)	N=21 12.2±5.9	N=23 12.4±5.3	0.94
HbF at Month 6 (end of intervention phase)	N=18 16.1±6.3	N=18 11.8±7.3	0.07
HbF at Month 6 Month 12 (end of sustainability phase)	N=22 14.2±5.0	N=18 14.1±9.3	0.98

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Figure. Primary outcome data for HbF (panel A) and HbF% deviation from personal best HbF (panel B) by difference-in-difference analysis, at enrollment, month 6 (end of intervention phase) and month 12 (end of sustainability phase). *within-group significant change (p=0.03).

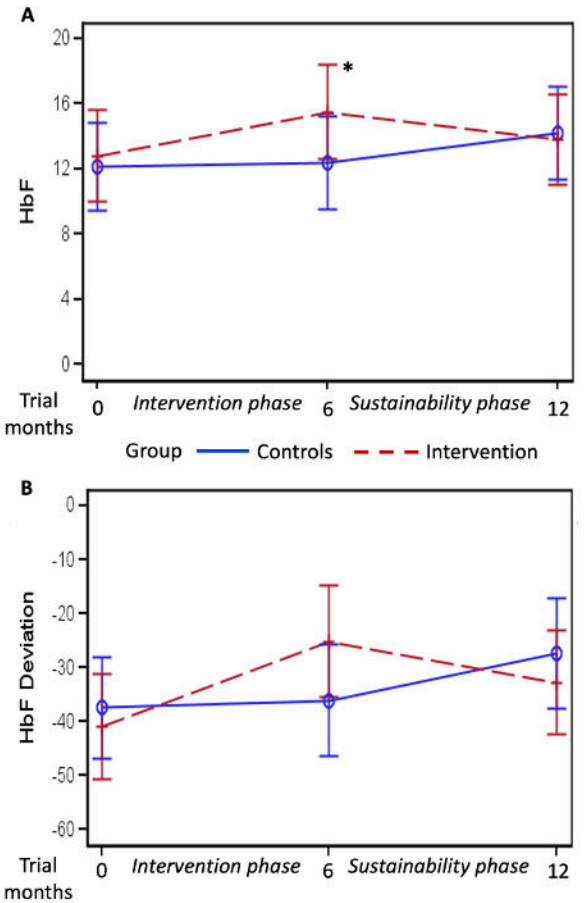

Figure 1