RANDOMIZED CONTROLLED TRIAL OF A MODIFIED DIRECTLY OBSERVED THERAPY APP FOR HCV TREATMENT DELIVERED IN NP-LED MOBILE HEALTH AND COMMUNITY HEALTH CENTERS IN RURAL AND URBAN SETTINGS

Authors:
King A[1], Kickham C[2], Boswell K[2], Roth P[1,3], Kramer E[2], Sivaraj L[1,3], Heo M[3], Litwin A[1,3]

1 Prisma Health, 2 Clemson Rural Health, 3 Clemson University

Background: Access to Hepatitis C (HCV) treatment is challenging in the United States, particularly in states that have not adopted Medicaid expansion. Nurse practitioners (NPs) can expand access to HCV care through low-threshold mobile health units (MHU) and community health centers (CHC). We compared the effectiveness of two treatment models – modified directly observed therapy (mDOT) versus treatment as usual (TAU) on treatment initiation, completion and SVR delivered in rural and urban settings in South Carolina.

Methods: Participants with current HCV – either newly screened at MHUs and health systems (emergency departments and hospital) or who were previously lost to follow-up – were eligible to enroll. MHUs performed HCV rapid antibody (Ab) testing at diverse locations (e.g., methadone programs, homeless shelters, and food pantries). The smartphone app encouraged participants to initiate HCV treatment via informational videos and provided virtual mDOT. Eligible HCV-infected participants were randomized (1:1) to mDOT vs. TAU and were offered treatment with DAAs at either NP-led MHU or CHC locations.

Results: Overall, 146 participants with HCV Ab+ were enrolled (88 MHU and 58 CHC). Among 115 HCV VL+ who were randomized (56 mDOT and 59 TAU), 34 mDOT (60.7%) and 31 TAU (52.5%) (p=0.453) initiated treatment, and 29 mDOT (51.8%) and 24 TAU (40.7%) completed treatment (p=0.265). Only 23 out of 45 (51.1%) eligible participants had SVR labs drawn, and 100% achieved SVR – 14 of 47 mDOT (29.8%) and 9 of 48 TAU (18.8%) (p=0.209).

Conclusion: The proportion who initiated and completed treatment did not differ between arms. NP-led models of care in both MHU and CHC settings led to high rates of HCV treatment initiation and completion for marginalized rural and urban populations. Treatment completion may be a more appropriate measure of HCV treatment success as nearly 50% were lost to follow-up after treatment completion.

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*F*igure 1. Percentage of patients in main treatment stages by treatment arm based on the randomized sample count.