Evidence Table 8: Key Questions 6a and 6c. Counseling Randomized Trials

| **Author, year Country Study name Overall Quality** | **Eligibility** | **Exclusion** | **Number screened/ eligible/ enrolled/ analyzed** | **Baseline characteristics** | **Intervention program** | **Duration of followup** | **Results** | **Funding source** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Groessl, 2011153 USA (VA San Diego Healthcare System)  Fair | US military veterans > 18 years of age with a confirmed diagnosis of chronic HCV, receiving care at VA Sand Diego Health Care system and willing to participate in a 6 weekly sessions of 2.5 hours in length. | Ongoing or scheduled to receive antiviral therapy, outside of geographic region, fatal co-morbid condition (life expectancy < 6 months), or receiving treatment for another life-threatening illness. | NR/327/137/132 (ITT) | Mean age: 54.6 years [Groups (A vs. B) significantly different in age 56.4 vs. 53.0 years; p=0.003] 5% Female 59% Non-Hispanic white 24% African American 10% Hispanics Marital status: 79% divorced, separated or never married | A: Information only: Educational booklet and handouts B: Self-management program (SMP): 6 weekly workshops based on self-management and cognitive-behavioral principles, each 2-2.5 hours | 6 weeks (end of program) | Information only vs. self-management program (p-value): 1) HCV knowledge change: 1.3 vs. 3.4 (p<0.0001) 2) HCV self-efficacy change: -0.09 vs. 0.75 (p= 0.01) 3) Energy change: 0.15 vs. 0.05 (p=0.46)  4) CES-D change: 1.0 vs. -0.7 (p=0.93) 5) Health distress change: 1.0 vs. -0.07 (p=0.06) 6) QWB change: 0.01 vs. 0.04 (p=0.26) 7) Global health status change (VAS 0-100): -0.4 vs. 5.5 (0.11) 8) SF-36 results (change in scores): a) Physical function: -3.6 vs. 3.3 (p=0.06)  b) General health: 1.8 vs. 1.1 (p=0.2) c) Body pain: 7.8 vs. 0.9 (p=0.07) d) PCS: 0.5 vs. 1.7 (p=0.4)  e) MCS: -0.5 vs. 0.6 (p=0.6) 9) HQLQ results (change in scores) a) Health distress (covariate=age): -3.3 vs. 3.6 (p=0.1) b) Positive well-being: 1.3 vs. 0.5 (p=0.8) c) HCV-specific limitations: 2.0 vs. -0.2 (p=0.6) d) HCV-specific health distress (covariate=age): -2.7 vs. 0.3 (p=0.5) | VA HSR&D Grant |
| Latka, 2008154 USAThe Study to Reduce Intravenous Exposures (STRIVE)  Fair | Aged 18 to 35 years, used injection drugs within 6 months, plans to live in area for 12 months, documented HCV-antibody positive and HIV-antibody negative serostatus, able to provide sample for liver function and HCV RNA testing, able to complete assessments and group sessions in English (recruited from a larger study of HIV- and HCV-negative injection drug users) | Not stated | 640/Not reported/418 (222 to behavioral intervention, 196 to control)/261 at 3 months | Age: 27 vs. 26 years  Female: 24% vs. 24%  Non-white: 43% vs. 43%  Aware of positive HCV status >6 months: 55% vs. 46%  Injecting at least once daily: 70% vs. 68% | A: Peer mentoring intervention: 6 sessions x hours, twice weekly, trained participants to be peer mentors for safer injection practices (hypothesized to reduce risky behaviors in the participants as well); content delivered via various methods including demonstrations, games, discussions, and videosB: Video discussion: 6 sessions x 2 hours, twice weekly | 6 months | Peer mentoring intervention vs. video discussionCombined distributive risk (how often lent used syringe, shared drug preparation equipment, divided drugs with syringe used by oneself): 44% vs. 59% at 3 months, p=0.02, AOR 0.46 (95% CI 0.27 to 0.79); 37% vs. 53% at 6 months, p=0.007, AOR 0.51 (95% CI 0.31-0.83)Frequency of lending used syringe to other: No differences at 3 months or 6 months (unadjusted)Frequency of preparing drugs with a syringe previously used by oneself: No differences at 3 months or 6 months (unadjusted)Frequency of sharing drug preparation equipment with or before someone else: 41% vs. 55%, at 3 months, p=0.03, AOR 0.47 (95% CI 0.27-0.82); 35% vs. 23% at 6 months, p=0.03, AOR 0.55 (95% CI 0.33-0.92)Refrained from injection drug use: 24% vs. 9.6% at 3 months, p=0.002, AOR 3.6 (95% CI 1.6-7.8); 34% vs. 23% at 6 months, p=0.03, AOR 1.6 (95% CI 0.96-2.7)Refrained from lending syringe because of HCV-positive status: 69% vs. 69% at 3 months, p=0.98, AOR 1.3 (95% CI 0.65-2.7); 67% vs. 60% at 6 months, p=0.39, AOR 1.5 (95% CI 0.74-3.0) | National Institute on Drug Abuse (NIDA) |
| Zule, 2009155 USA  Fair | At least 18 years of age, self-reported IDU in previous 30 days, visible tracks or positive urine specimen for heroin, cocaine, or methamphetamine, no formal substance abuse treatment in previous 30 days and current residence in area of study. | Not stated | 861/855/847/625  Note: 1286 (of 1786) met preliminary eligibility criteria | Mean age: 41.2 years, 9.3 SD  66% African American  27% Non-Hispanic while  7% Other  27% Female  55% HCV positive  Risk Behaviors (in past 30 days):70% used alcohol 17% shared syringe 23% shared cooker, cotton or rinse water  27% > 1 sexual partner  57% unprotected at last sexual intercourse | A. Motivational intervention: 6 sessions including 2 cue-card sessions presented by PowerPoint. First session included 20 slides adapted from NIDA; 2nd session included 24 slides (number depended on test results) and additional sessions focused increasing motivation to change, eloping a plan for change, reviewing progress and reaffirming committments to change.B. Educational intervention: 6 sessions with first 2 session based on cue cards from the NIDA and followed up with 4 additional sessions with videos of 1 hour in length. Topics included hepatitis A, B, C; indirect screening practices; and addiction.Note: participants screened for HCV and given results during the study. | 12 months | Motivational intervention vs. educational education, HCV positive participants: OR (95% CI)  Alcohol use (in past 30 days):  1) 6 months followup: 0.65 (0.44, 0.94))  2) 12 months followup: 0.94 (0.64-1.38)  Other results not stratified by those HCV positive | NIDA and NIH |