



Full length article

## Effect of a primary care based brief intervention trial among risky drug users on health-related quality of life



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### ABSTRACT

**Background:** Improvement in quality of life (QOL) is a long term goal of drug treatment. Although some brief interventions have been found to reduce illicit drug use, no trial among adult risky (moderate non-dependent) drug users has tested effects on health-related quality of life.

**Methods:** A single-blind randomized controlled trial of patients enrolled from February 2011 to November 2012 was conducted in waiting rooms of five federally qualified health centers. 413 adult primary care patients were identified as risky drug users using the WHO-ASSIST and 334 (81% response; 171 intervention, 163 control) consented to participate in the trial. Three-month follow-ups were completed by 261 patients (78%). Intervention patients received the QUIT intervention of brief clinician advice and up to two drug-use health telephone sessions. The control group received usual care and information on cancer screening. Outcomes were three-month changes in the Short Form Health Survey (SF-12) mental health component summary score (MCS) and physical health component summary score (PCS).

**Results:** The average treatment effect (ATE) was non-significant for MCS (0.2 points,  $p$ -value = 0.87) and marginally significant for PCS (1.7 points,  $p$ -value = 0.08). The average treatment effect on the treated (ATT) was 0.1 ( $p$ -value = 0.93) for MCS and 1.9 ( $p$ -value = 0.056) for PCS. The effect on PCS was stronger at higher (above median) baseline number of drug use days: ATE = 2.7,  $p$ -value = 0.04; ATT = 3.21,  $p$ -value = 0.02.

**Conclusions:** The trial found a marginally significant effect on improvement in PCS, and significant and stronger effect on the SF-12 physical component among patients with greater frequency of initial drug use.

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## 1. Introduction

Illicit drug use carries a substantial burden given its high prevalence and negative impact on individuals, families, and communities. The estimated cost of illicit drug use in the U.S. is similar to that of other substances—around \$181 billion per year compared to \$185 billion for alcohol and \$193 billion for tobacco (U.S. Department of Justice and National Drug Intelligence Center, 2011). At the population level, preventive interventions need to

be undertaken where large groups of individuals seek services on a regular basis. Primary care clinics have regular contact with large, multi-ethnic groups. In primary care, routines and guidelines regarding screening, brief intervention, and referral to treatment (SBIRT) can be implemented (Kamerow et al., 1986; Saitz et al., 2010). There is evidence that reduction in illicit drug use can be achieved using behavior change theories and techniques (Babor et al., 2007; Bernstein et al., 2005; Goldstein et al., 2004; Humeniuk et al., 2008b, 2012; Humphreys and McLellan, 2010). Screening for risky (or problematic) non-dependent drug use in primary care settings followed by brief intervention using provider advice and counseling might interrupt progression to drug dependence and reduce levels of use. Successful brief interventions for drug users

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not yet dependent provide a cost-effective alternative to the referral to specialized drug treatment required for dependent patients (Humeniuk et al., 2012; John et al., 2013).

While brief interventions have been shown to reduce illicit drug use in outpatient and inpatient settings (Babor et al., 2007; Bernstein et al., 2005; Goldstein et al., 2004; Humeniuk et al., 2008b, 2012; Humphreys and McLellan, 2010), reduced substance use is not, in itself, an adequate criterion for recovery (Donovan, 2012). Reduced substance use or cessation is an important starting-point but a final aim of drug treatment should be to improve patient-centered outcomes (Andersen et al., 2014; Miller and Miller, 2009). ‘Substance abusers seek help quitting drugs not as an end in itself, but as a means to escape the negative consequences and to gain a better life’ (Laudet, 2011). Accordingly, while substance abuse treatment seeks to promote abstinence or reduction in substance use, its ultimate aim is to improve the patient’s quality of life (QOL). Patients want substance abuse treatment to impact very general aspects of QOL—individuals’ perception of their position in life within the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns (World Health Organization, 1995). However, the drug addiction field lags behind in acknowledging QOL as an essential outcome of care. Most published studies are on QOL in alcohol dependency and very few involve illicit drug use (Laudet, 2011). Most QOL studies in drug users were conducted outside of the US and few have examined drugs other than opiates (Laudet, 2011).

Expectedly, QOL is worse among substance-dependent individuals and substance abuse treatment seekers compared to the general population (Donovan et al., 2005; Laudet, 2011). Reduction in substance abuse or abstinence is positively correlated with improvements in QOL (De Maeyer et al., 2010). Observational studies suggest that QOL improves during substance abuse treatment (De Maeyer et al., 2011a, 2011b, 2013; Tracy et al., 2012). Few trials have tested effects on QOL. An analysis of three trials, which were conducted in community-based outpatient treatment centers for cocaine abuse in Connecticut and Massachusetts ( $n = 393$ ), showed that contingency management was associated with improvement in QOL nine months after randomization (Andrade et al., 2012). Another study of 252 adults in an effectiveness trial of a cognitive behavioral treatment for substance abuse found no substantial effect on QOL after three months (Morgan et al., 2003). Evidence from brief interventions for drug abuse on QOL outcomes from randomized studies is sparse. A brief intervention trial among adolescents achieved reduction in drug use, which was paralleled by improvement in quality of life (Becker et al., 2009, 2011).

Given these inconclusive findings, we used data from the Quit Using Drugs Intervention Trial (QUIT; Gelberg et al., submitted), a brief intervention conducted in federally qualified health centers (FQHCs) among racially diverse, low-income adult patients with risky (non-dependent) drug use to investigate effects on change in health-related QOL (HRQOL) over three months. Since studies have not consistently shown effects on domains of QOL other than mental functioning (Laudet, 2011), we tested treatment effects on both the mental and physical dimensions of HRQOL. In addition, because our previous analysis found QUIT to impact drug use more strongly in those with greater frequency of initial drug use (Gelberg et al., submitted), we performed exploratory subgroup analyses according to levels of initial drug use.

## 2. Methods

QUIT was a single-blind randomized controlled trial in five FQHCs in Los Angeles County (LAC). Details of the protocol, brief intervention and primary outcomes have been described elsewhere (Gelberg et al., submitted). The alcohol, smoking and substance

involvement screening test (ASSIST) was used to screen for problem or risky drug use (Humeniuk et al., 2006, 2008a; McNeely et al., 2014). It contains seven questions about nine substance categories: tobacco, alcohol, marijuana, crack/cocaine, methamphetamine/amphetamine type stimulants, inhalants, sedatives, hallucinogens, and opioids. A score was determined for each substance and is categorized as low, moderate or high risk. The ability of the ASSIST to classify patients based on degree of drug use has been extensively validated (Humeniuk et al., 2008a, 2012). Based on the ASSIST, patients’ use of each drug category (excluding alcohol and tobacco) was scored as: no or low use requiring no intervention (score 0–3); risky use (moderate, non-dependent) requiring clinician brief advice (score 4–26); or high use (most likely dependent) requiring referral (score 27 and above).

### 2.1. Settings

The clinics were mostly large FQHCs in LAC. Clinic selection was based on robust patient encounter volumes among LAC safety net clinics and consultation with experts on local areas most affected by drug use. Recruitment and enrollment spanned 22 months from February 2011 to November 2012. All five clinics approached agreed to participate.

### 2.2. Inclusion and exclusion criteria

All persons present in clinic waiting rooms were screened and included in the trial if they were patients at the clinic for a primary care visit and: (1) were risky illicit drug users during the prior three months (ASSIST score between 4 and 26); (2) were 18 or older; (3) spoke English or Spanish; (4) expected to be living in the LAC area for the next 3 months; and (5) had an active phone number. Persons at the clinic were excluded if they: (1) were not patients at the clinic for a primary care visit; (2) were not illicit drug users or used infrequently (ASSIST score 0–3); (3) were dependent illicit drug users (ASSIST score  $\geq 27$ ); (4) had been under drug treatment for more than 30 days or (5) were pregnant.

### 2.3. Randomization

The trial used urn randomization at the patient level for the control ( $n = 163$ ) and intervention group ( $n = 171$ ), with blocking on two strata of the level of drug use (i.e., ASSIST score 4–16, 17–26) (Stout et al., 1994).

### 2.4. Incentives and consent

Patients were paid \$30 for the initial assessment, \$50 for the follow-up assessment and participated in a \$500 lottery if they completed all study activities required for the intervention or control condition (as described below). Informed consent was obtained—orally for screening and in writing if they qualified for enrollment. The text of the consent and pre-ASSIST eligibility questions masked the purpose of the study, naming it as the “Living Well Study” to promote healthy lifestyles. The research protocol was approved by the University of California, Los Angeles, Human Subjects Protection Committee.

### 2.5. Interventions

After the screening process, intervention patients received a brief primary care intervention. They subsequently received a Health Education Booklet and a drug-specific Report Card for their highest ASSIST-scoring drug in the risky range, and viewed an intervention Video Doctor reinforcing the clinicians’ message (Gilbert et al., 2008).

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