Adherence to Isoniazid Prophylaxis in the Homeless

A Randomized Controlled Trial

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Objectives: To test 2 interventions to improve adherence to isoniazid preventive therapy for tuberculosis in homeless adults. We compared (1) biweekly directly observed preventive therapy using a $5 monetary incentive and (2) biweekly directly observed preventive therapy using a peer health adviser, with (3) usual care at the tuberculosis clinic.

Methods: Randomized controlled trial in tuberculosis-infected homeless adults. Outcomes were completion of 6 months of isoniazid treatment and number of months of isoniazid dispensed.

Results: A total of 118 subjects were randomized to the 3 arms of the study. Completion in the monetary incentive arm was significantly better than in the peer health adviser arm ($P = .01$) and the usual care arm ($P = .04$), by log-rank test. Overall, 19 subjects (44%) in the monetary incentive arm completed preventive therapy compared with 7 (19%) in the peer health adviser arm ($P = .02$) and 10 (26%) in the usual care arm ($P = .11$). The median number of months of isoniazid dispensed was 5 in the monetary incentive arm vs 2 months in the peer health adviser arm ($P = .005$) and 2 months in the usual care arm ($P = .04$). In multivariate analysis, independent predictors of completion were being in the monetary incentive arm (odds ratio, 2.57; 95% CI, 1.11-5.94) and residence in a hotel or other stable housing at entry into the study vs residence on the street or in a shelter at entry (odds ratio, 2.33; 95% CI, 1.00-5.47).

Conclusions: A $5 biweekly cash incentive improved adherence to tuberculosis preventive therapy compared with a peer intervention or usual care. Living in a hotel or apartment at the start of treatment also predicted the completion of therapy.

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The homeless in the United States are at high risk for tuberculous infection and for active tuberculosis (TB) as well as for human immunodeficiency virus (HIV) infection. In a representative sample of homeless adults in San Francisco, Calif, from 1990 to 1994, 32% were tuberculin skin test (TST) positive and 9% were seropositive for HIV. A DNA fingerprinting study in Los Angeles found a high rate of clustering of restriction fragment length polymorphisms in TB cultures from the downtown homeless population, suggesting frequent recent transmission with rapid progression to disease. The homeless appear to have a high rate of ongoing TB transmission, and should be considered a high-priority population for TB control.

Screening for TB and subsequent preventive therapy with isoniazid are well-established tools of TB control. However, both are thought to be difficult to implement in the homeless population. In a study of appointment keeping to the San Francisco TB clinic, it was found that only 53% of TST-positive homeless persons kept their referral to the clinic. In a study of isoniazid preventive therapy offered in a Seattle, Wash, men’s shelter, the overall completion rate was 49%. In San Francisco, the rate of completion in homeless adults has been thought to be too low to justify routine use of isoniazid prophylaxis. The Centers for Disease Control and Prevention has declared the homeless a high-risk group for developing TB, but its own guidelines suggest that preventive therapy with isoniazid is unlikely to be successful in the homeless because of poor adherence.

Directly observed therapy has been shown to improve adherence to treatment for active TB even in hard-to-treat populations. We set out to investigate whether biweekly directly observed...
SUBJECTS AND METHODS

STUDY DESIGN
We conducted a 2-phase randomized controlled trial of 2 methods of improving adherence to isoniazid vs usual care. In the first phase, we examined interventions to improve appointment keeping at the TB clinic for diagnostic testing.7 In the second phase of the study, reported herein, all subjects who completed referral and were prescribed preventive therapy by physicians at the TB clinic were kept in their originally assigned arms for a 6-month course of isoniazid preventive therapy. Both phases of the study were approved by the Committee on Human Research of the University of California, San Francisco. Subjects consented to randomization after discussion of the differences between the 3 arms of the study.

STUDY POPULATION
Recruitment was from 2 sources. First, from 1991 to 1994 the San Francisco General Hospital Homeless Study screened a representative sample of homeless and marginally housed adults for HIV and TB infection.1 Subjects were recruited, interviewed, and tested in emergency shelters, free meal lines, and low-cost residential hotels. The TST was done using the standard Mantoux method with a 3–tuberculin unit purified protein derivative solution. An induration of 10 mm in HIV-negative persons and 5 mm in HIV-positive persons was considered a positive result. All subjects who returned for HIV and TB skin test results within 1 week of being interviewed were evaluated for the present study.

In the last year of the study, subjects were also recruited from TB screenings in low-cost residential hotels in the inner-city neighborhoods of San Francisco carried out by the San Francisco Department of Public Health Division of TB Control. These screenings were part of a TB surveillance project targeting residents in low-cost residential hotels. The hotels were similar in cost, location, and clientele to those screened in the San Francisco General Hospital Homeless Study.

INCLUSION AND EXCLUSION CRITERIA
Subjects who had either a positive TST result by Centers for Disease Control and Prevention criteria6 or a credible history of a prior positive TST result but no follow-up in the previous 6 months were eligible. Fluency in spoken Spanish or English was required. Subjects currently receiving prophylaxis or treatment for TB disease and those known to be HIV positive were excluded. Subjects who completed a visit to the TB clinic and accepted a recommendation to take isoniazid preventive therapy for 6 months or more were enrolled. Subjects started on treatment for active TB during the first TB clinic visit were excluded, but those whose isoniazid treatment was delayed pending further evaluation (eg, blood tests or sputum examination for TB) were included if isoniazid was eventually dispensed. All decisions about starting or stopping isoniazid therapy were made by TB clinic staff and study subjects together and were based on standard Centers for Disease Control and Prevention criteria.6

Most subjects in this study were “literally homeless,” defined as individuals staying in an emergency shelter, a street, car or van, in a park, or in any other outdoor public space not designated for sleeping, or “marginally housed,” defined as indigent residents of low-cost residential hotels often referred to as single room occupancy hotels. These hotels require no security or rent deposits. Some subjects living in apartments were recruited from free meal lines.

STUDY PROCEDURES

Recruitment into the study took place after all subjects were given notification of HIV and TST results by trained clinical staff. Each subject agreeing to the study was given an appointment to the TB clinic at a time chosen by the subject, provided with bus tokens and directions to the clinic, and randomized to the intervention or control arms. Those refusing to participate were also given appointments, bus tokens, and directions to the clinic. A block randomization method was used in which one third of consenting subjects were assigned to each arm at each screening. To carry out the randomization, subjects made a blinded selection of labeled coins taken from a bag.

If preventive therapy was prescribed at the TB clinic, subjects randomized to the monetary incentive and peer health advisor arms received DOPT with 900 mg of isoniazid given twice weekly for 6 months. Subjects in the usual care arm were given 1 month’s supply of 300-mg isoniazid with instructions on daily dosing and were given return appointments to the clinic monthly for 6 months. All subjects in all 3 arms were seen at the TB clinic monthly for review and refills of isoniazid. The intervention arms were designed to be supplementary to normal care at the TB clinic. A subject was considered lost to follow-up if the TB clinic restarted the full 6-month course of isoniazid after the subject missed 1 or more months of therapy or if the TB clinic discharged the patient from care for being lost to follow-up.

Monetary Incentive Arm
Subjects took an observed dose of 900 mg of isoniazid at each of 2 weekly visits to a study site near the TB clinic and received $5 each time. If the TB clinic ordered a delay in starting isoniazid, a subject was paid twice a week for a symptom review until isoniazid was prescribed. Each dose taken was observed by a research assistant who also monitored the subjects for side effects. Problems were immediately referred to the physician investigators (J.P.T., L.P., and A.J.Z.) or to the TB clinic. If a dose of isoniazid was missed, attempts to contact the subject were made through

preventive therapy (DOPT) with 900 mg of isoniazid could be successfully offered to a homeless population. This regimen has been recommended for populations where adherence may be poor.12 We report the results of the second part of a randomized controlled trial of interventions for improving adherence to isoniazid preventive therapy in the homeless. We examined 2 ways of providing biweekly DOPT to the home-
letters or telephone calls. Research assistants managing this arm were laypersons trained by study physicians. They were encouraged to be friendly and respectful to the subjects, but were explicitly discouraged from giving special assistance or medical referrals. Subjects were referred to the TB clinic for any supplementary medical or social services requested or needed by the subjects.

**Peer Health Adviser Arm**

Each subject was introduced to a peer health adviser immediately after randomization. The peer health adviser was responsible for providing 900 mg of isoniazid for DOPT to the subject twice weekly and observing the subject take each dose. For subjects whose isoniazid was not dispensed immediately by the TB clinic pending the results of further testing, the peer health adviser visited the subject twice a week for a review of TB symptoms. The peer health adviser was instructed to check for side effects before each dose of isoniazid was administered using the TB clinic review protocol. Any symptoms reported that could be an isoniazid side effect was referred immediately to the physician investigators and isoniazid was held until evaluation by the TB clinic. The peer health adviser accompanied his or her client to the clinic for monthly refill appointments. If a subject missed a dose or a monthly TB clinic appointment, the peer health adviser was instructed to spend an allotted amount of time looking for the subject. A subject was assigned to one peer health adviser and was not routinely changed to another peer health adviser during the course of treatment.

Peer health advisers were employed by the University of California as temporary hourly staff for 12 hours a week at $8.98 per hour, independent of caseload. They were issued beepers and given bus passes. Candidates for positions were referred by service organizations and providers working with the homeless. Candidates were required to demonstrate reliability, a caring and responsible attitude, and the ability to acquire basic medical knowledge about TB and HIV. All peer health advisers were homeless at time of hire or had been homeless during the previous year. During 3 years of the study, 20 persons were interviewed and 8 were hired.

**Usual Care Arm**

The usual care arm followed the routine practices of the TB clinic. Clinic staff instructed subjects who were prescribed isoniazid in daily self-administered dosing. Subjects were then given 1 month’s supply of pills and scheduled for monthly drop-in appointments at the TB clinic for symptoms review and isoniazid refills. Adherence to monthly refill appointments was monitored by reviewing TB clinic charts. For subjects failing to return for refill appointments, the clinic followed a standard contact protocol with either 3 letters or 3 telephone calls before closing the chart to further isoniazid treatment. It should be noted that both intervention arms were directly observed but the control arm was not. Subjects in the control arm were assumed to be adherent if they picked up their monthly refill.

**CHANGE IN PROTOCOL**

An analysis of adherence to referral to the TB clinic showed that appointment keeping was significantly greater in the monetary incentive arm of the study (85%) than in the usual care arm (54%). In response to ethical concerns about not completing screening for active TB and after outside consultation, the protocol was modified to offer all subjects a $5 incentive to keep initial appointments at the TB clinic. Randomization to the 3 arms for 6 months of isoniazid prophylaxis continued unchanged at the time of recruitment. Only those randomized to the monetary incentive arm continued to get cash during the dispensing of isoniazid. There were 27 subjects recruited into the study after this change took place. There were no significant differences in demographic characteristics or adherence behavior between those in the original group and those recruited after the change in protocol.

**OUTCOMES**

The primary outcome of the study was completion of 6 months of isoniazid preventive therapy as documented by the TB clinic chart. The DOPT allowed us to document each dose in the peer health adviser and monetary incentive arms, but self-report during monthly refill visit was used as a surrogate for adherence in the usual care arm. This is the standard practice in TB clinics throughout the United States.

**STATISTICAL ANALYSIS**

Wilcoxon rank sum tests were used to determine if continuous variables were distributed equally among the 3 arms of the study, and also to determine if the continuous variables were different in the adherent and nonadherent groups. χ² Tests or the Fisher exact test were used for analyses of categorical variables. Probability of adherence over months of isoniazid prescribed was estimated using Kaplan-Meier methods. The x-axis in the figure is not calendar time but months receiving isoniazid because subjects were allowed to reenter the study after breaks in therapy of 1 or 2 months. Number of months of isoniazid received was right-censored at 6 months. We included as censored 3 subjects who did not complete isoniazid treatment because dispensing of the drug was stopped by the TB clinic due to concern about toxic effects. Confidence intervals (CIs) for the estimates were calculated using Greenwood’s formula. The log-rank test was used to determine if the adherence curves differed between groups. Variables that were associated with adherence in bivariate analysis (P<.10) were entered into a forward stepwise logistic regression model, with significance level for entry set at .10 because of the sample size. We compared the monetary incentive arm with the other 2 arms combined to provide sufficient numbers for analysis.
RESULTS

RECRUITMENT

From June 1992 through December 1994, a total of 2158 subjects were screened. A total of 618 (29%) had either a positive TST result or a history of being TST positive. Eighty-nine (4%) of these refused to be randomized into the study. The most common reasons for refusal were desire to follow up with one’s own provider or objection to the randomization process. One hundred ninety-nine subjects (32%) were ineligible because of failure to return for results, HIV infection, screening for TB with a chest x-ray in the last 6 months, or current treatment with isoniazid. A total of 330 eligible subjects were therefore recruited. These subjects were randomized into the 3 arms, and followed through their appointments at the TB clinic for further screening and possible prescription of isoniazid. At the clinic, 195 of the 330 subjects were found not to require further evaluation and 37 were found to require further diagnostic testing such as sputum cultures or baseline liver function tests. A total of 121 (37%) of these 330 were ultimately prescribed isoniazid, including 23 (62%) of 37 requiring further testing. Three of the 121 subjects who started isoniazid therapy had their isoniazid stopped by the TB clinic due to suspected toxic effects; thus, 118 subjects are analyzed here.

DEMOGRAPHIC AND BEHAVIORAL CHARACTERISTICS

Forty-three subjects were randomized to the monetary incentive arm, 37 to the peer health adviser arm, and 38 to the usual care arm. Characteristics of the 118 subjects by randomization arm are listed in Table 1. Overall, on the night before screening 58% had stayed in a shelter; 21% in a low-cost residential hotel; 10% on the streets or in cars; 11% with friends, relatives, or in their own apartment. Nearly 30% had completed some college and 31% were veterans. The median time since last employment was 14 months and 78% had used a free meal program in the past month in San Francisco. More than 30% had a lifetime history of injection drug use, 64% had used crack cocaine, and 56% met a standardized screening criteria for history of alcoholism. Current use of drugs and alcohol was also high (Table 1). Fifteen percent had been hospitalized overnight for psychiatric illness at least once. There were no significant differences in demographic or behavioral variables between the 3 arms of the study.

ADHERENCE TO ISONIAZID PROPHYLAXIS

The Figure shows proportions of subjects adherent at each month of therapy prescribed.

Completion in the monetary incentive arm was significantly better than in the peer health adviser arm (P = .01) and the usual care arm (P = .04), by log-rank test. The difference between the peer health adviser and usual care arms was not statistically significant. In each group the failure rate was greatest between the first and second months of isoniazid preventive therapy. Nineteen subjects (44%) in the monetary incentive arm completed 6 months of isoniazid treatment compared with 7 (19%) in the peer health adviser arm (P = .02) and 10 (26%) in the usual care arm (P = .11).

Overall, 36 (31%) of 118 subjects completed 6 months of isoniazid preventive therapy. The median number of months of isoniazid dispensed was 5 in the monetary incentive arm, significantly greater than in the peer health adviser arm (2 months; P = .005) or the usual care arm (2 months; P = .04).

The probability of receiving at least 3 months of isoniazid therapy was 53% (95% CI, 45%-63%). It was 71%
(95% CI, 59%-86%) in the monetary incentive arm, 42% (95% CI, 29%-61%) in the peer health adviser arm, and 45% (95% CI, 31%-64%) in the usual care arm.

We examined the influence of demographic and behavioral variables on adherence across the 3 arms of the study combined (Table 2). Only housing status at the time of entry into the study was a statistically significant predictor of adherence to 6 months of isoniazid therapy. Subjects who were literally homeless living in a shelter or on the street were much less likely to complete treatment than those living in hotels or apartments or living with friends ($P = .05$).

We combined the peer health adviser and the usual care arms to provide sufficient numbers for a multivariate analysis of behavioral and demographic variables and study arm. Completion of 6 months of isoniazid prophylaxis was significantly better in the monetary incentive arm than the other 2 arms combined (odds ratio, 2.57; 95% CI, 1.11-5.94; $P = .03$), and housing status was an independent predictor of completion (odds ratio, 2.33; 95% CI, 1.00-5.47; $P = .05$). The unadjusted odds ratios were 2.70 and 2.29, respectively.

**COMMENT**

Although the incidence of TB disease is declining in the United States, it has been recommended to TB control units that to prevent an upswing in cases, control activities must concentrate on prevention.14,15 Several observational studies have documented the problems of adherence to preventive treatment in difficult populations such as the homeless.16,17 We report a randomized, controlled trial of 2 interventions with DOPT to improve adherence to preventive therapy in the literally homeless and marginally housed in San Francisco.

In our study, 121 persons screened and recruited at meal lines, shelters, and hotels and started on isoniazid preventive therapy were randomized to a biweekly monetary incentive, a peer health adviser, or usual care. Only 3 subjects had their isoniazid regimen stopped by the TB clinic because of documented or perceived side effects. Among the remainder, we found that 44% of subjects adhered to a course of twice-weekly DOPT in the monetary incentive arm, vs 19% of those assigned a peer health adviser and 26% of those assigned to (unobserved) usual care. Completion of 6 months of therapy was better in the monetary incentive arm than in each of the other arms by log rank test, with a significantly higher completion rate than the peer health adviser arm, and a marginally higher rate than the usual care arm. The median number of months of isoniazid dispensed was significantly greater in the monetary incentive arm than in either of the other arms. Of the subjects in the monetary incentive arm, 71% completed 3 or more months of isoniazid treatment, the minimum thought to produce a detectable benefit.12 In summary, the monetary incentive arm produced a moderate improvement in adherence when compared with the other arms of the study.

The only other variable predicting adherence in this study was housing status; subjects who lived in hotels or apartments had an independent adjusted odds ratio for completion of 2.33 vs the “literally homeless” who lived in shelters or on the street ($P = .05$). Stable housing is often considered a key requirement for providing effective medical care in the homeless8,17,18 and our study supports this. In the monetary incentive arm, the completion rate among those living in low-cost residential hotels was 70%. In San Francisco the indigent hotel population is at least twice as large as the literally homeless population and has the same rate of TB infection. Finally, although drug and alcohol use and mental illness are often cited as barriers to adherence in the homeless, our study, like others, found no association between these variables and adherence.10,17

No were race, sex, or age predictive of adherence.

This study is one of the few controlled trials on the use of incentives in clinical or behavioral medicine for improving adherence to TB treatments.17,20,21 Additional studies have used incentives to enhance adherence to TB screening alone, but not with a control arm.22,23 A recent review of studies using incentives for patient adherence listed the first phase of our present study as one of only 11 studies meeting standard criteria for adequate methodology in evaluating the role of incentives.24 Ours is the only study using a community-based approach for the recruitment of a homeless population into TB prevention studies. We accepted all consenting participants in a screening of street and shelter dwellers and meal-line users, including in particular those who were marginally housed in low-cost residential hotels.

Cash and noncash incentives have been discussed widely in TB control but few studies have been carried out. One uncontrolled study of TB treatment in India used varying amounts of the patient’s own money as incen-

### Table 2. Univariate Predictors of Completion of 6 Months of Isoniazid Preventive Therapy

<table>
<thead>
<tr>
<th>Predictor</th>
<th>No. Completing (%)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>30/102 (29)</td>
<td>.56</td>
</tr>
<tr>
<td>Female</td>
<td>6/16 (38)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
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<td></td>
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<tr>
<td>African American</td>
<td>20/61 (33)</td>
<td>.61</td>
</tr>
<tr>
<td>Hispanic or other</td>
<td>10/32 (31)</td>
<td>.77</td>
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<tr>
<td>White</td>
<td>6/25 (24)</td>
<td>.83</td>
</tr>
<tr>
<td><strong>Age, y</strong></td>
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<td></td>
</tr>
<tr>
<td>≤40</td>
<td>24/25 (96)</td>
<td>.76</td>
</tr>
<tr>
<td>&gt;40</td>
<td>12/41 (29)</td>
<td></td>
</tr>
<tr>
<td><strong>Ever in jail or prison</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24/36 (67)</td>
<td>.18</td>
</tr>
<tr>
<td>No</td>
<td>11/46 (24)</td>
<td></td>
</tr>
<tr>
<td><strong>Residence</strong></td>
<td></td>
<td></td>
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<tr>
<td>Street or shelter</td>
<td>19/26 (73)</td>
<td>.05</td>
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<tr>
<td>Home or hotel</td>
<td>16/37 (43)</td>
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<td><strong>Injecting drug use past 30 d</strong></td>
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<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4/12 (33)</td>
<td>.87</td>
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<tr>
<td>No</td>
<td>22/31 (71)</td>
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<td><strong>Crack cocaine use past 30 d</strong></td>
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<tr>
<td>Yes</td>
<td>13/33 (39)</td>
<td>.83</td>
</tr>
<tr>
<td>No</td>
<td>22/72 (31)</td>
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<tr>
<td><strong>No. of alcoholic drinks in prior week</strong></td>
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<tr>
<td>≤20</td>
<td>24/45 (54)</td>
<td>.22</td>
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<td>&gt;20</td>
<td>11/41 (27)</td>
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<td><strong>History of mental illness</strong></td>
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<td>Yes</td>
<td>8/17 (47)</td>
<td>.12</td>
</tr>
<tr>
<td>No</td>
<td>27/56 (28)</td>
<td></td>
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</table>

* Referent group.
tives. The patient’s money was deposited at the beginning of treatment and returned only on completion. The larger the deposit, the more likely a patient was to complete treatment.22 It should be noted that noncash incentives such as food vouchers are often used in TB control because of concerns about the use of cash as an incentive. Some health care providers believe that it is inappropriate to give money to persons with known alcohol or drug addictions.24 However, no controlled studies have compared cash with noncash approaches. We suggest that the role of different types of incentives needs to be discussed for active TB as well as for preventive therapy. Detention for persons who do not adhere to TB therapy is used throughout the United States.22 Studies such as ours may assist in the development of techniques that are less coercive that can also be used for patients with active TB.

We observed 2 specific barriers to adherence: (1) distance between the neighborhoods where most of the homeless spend their time and the county hospital where the TB clinic and our monetary incentive arm were based, and (2) jail. Most of the homeless services and low-cost hotels are at least 30 minutes walking distance from the hospital and TB clinic. Improving access by providing a convenient downtown site for DOPT might well improve adherence. In addition, nearly 60% of our subjects had been in jail or prison before the study and at least 5% of the subjects went to jail during the course of the study. Formal communication with the jail medical staff could have improved adherence since jail staff will provide isoniazid in jail and refer subjects back to the study upon release.

Although the peer health adviser intervention was successful in improving adherence to initial referral to the TB clinic, it was not successful in improving adherence to 6 months of isoniazid therapy. This was surprising to the study investigators and was discussed with study staff. Staff members noted (1) that the peer health advisers were often themselves struggling with problems comparable to those of their clients, (2) that they did not know how to address the barriers to adherence erected by their clients (“no time to meet,” “inconvenient to wait for my peer health adviser,” “forgot about plans to meet,” “too far to go to the TB clinic for refills”), (3) that they sometimes became frustrated that their clients did not seem to share the advisers’ concern about TB prevention, and (4) that the advisers were often unable to problem solve with their clients on a moment-to-moment basis. These comments are similar to reports on community worker interventions from other studies.28-30 Additional training in problem solving with clients, and also a higher level of supervision, might have improved adherence in this arm, but would have increased the cost of the intervention. Because of the cost of the advisers themselves, the peer health adviser intervention is about 1.5 times as expensive as the monetary incentive intervention.

The present results suggest that a $5 monetary incentive for twice-weekly DOPT may improve adherence in homeless populations, especially in those who are marginally housed. We found that risk factors sometimes believed to predict nonadherence (eg, alcohol use, drug use, and mental illness) were not significant predictors of adherence to completion of isoniazid treatment. We suggest that twice-weekly DOPT with a $5 incentive be considered as a prevention strategy by jurisdictions with large numbers of TB cases among the homeless and marginally housed.

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REFERENCES