The most common levels of care in U.S. substance abuse treatment programs are Outpatient (OP) and Intensive Outpatient (IOP).

- OP typically consists of 2 - 8 service hours per week
- IOP typically consists of 9 or more service hours per week

The Baltimore Buprenorphine Initiative integrated buprenorphine into formerly drug-free outpatient treatment programs.

### METHODS

#### Design
2-arm parallel randomized controlled trial (RCT) comparing OP vs. IOP care.

#### Sample of Interest
African Americans entering outpatient buprenorphine treatment (n = 300).

#### Sites
2 outpatient community treatment programs.
- Both sites were part of the Baltimore Buprenorphine Initiative and provided primarily group-based counseling with individual counseling available.

#### Focal Measures
World Health Organization Quality of Life (QoL) Scale (WHO-BREF).
- Physical, Psychological, Social, and Environmental QoL Domains

#### Follow-up
Follow-up interviews were conducted at 3 months (follow-up rate > 95%).

#### Analysis
Generalized Estimating Equations (GEE) to answer 3 key questions

### Table 1. Participant Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sample (N=300)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female Gender, n (%)</td>
<td>113 (37.67)</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>46.09 (6.45)</td>
</tr>
<tr>
<td>Married, n (%)</td>
<td>31 (10.33)</td>
</tr>
<tr>
<td>Employed in past 30 days, n (%)</td>
<td>108 (36.00)</td>
</tr>
<tr>
<td>Years of Education, mean (SD)</td>
<td>11.48 (1.61)</td>
</tr>
<tr>
<td>Previous Opioid Pharmacotherapy</td>
<td>92 (30.67)</td>
</tr>
<tr>
<td>No previous opiate agonist treatment, n (%)</td>
<td>87 (29.00)</td>
</tr>
<tr>
<td>Previous buprenorphine treatment only, n (%)</td>
<td>55 (18.33)</td>
</tr>
<tr>
<td>Previous methadone treatment only, n (%)</td>
<td>66 (22.00)</td>
</tr>
</tbody>
</table>

**Previous Opioid Pharmacotherapy**

No previous opiate agonist treatment, n (%) | 92 (30.67)
Previous buprenorphine treatment only, n (%) | 87 (29.00)
Previous methadone treatment only, n (%) | 55 (18.33)
Previous buprenorphine and methadone treatment, n (%) | 66 (22.00)

**Drug Use Characteristics**

Injection drug user, n (%) | 70 (23.33)
Cocaine use in last 30 days or cocaine+ urine, n (%) | 184 (61.33)
DSM-IV dependence: opioids, n (%) | 282 (94.00)
DSM-IV dependence: cocaine, n (%) | 121 (40.47)
Days of heroin use in last 30, mean (SD) | 22.29 (9.62)
Days of cocaine use in last 30, mean (SD) | 7.18 (10.56)

**R**

**Psychological QoL:**

+ 10.8 % (p<.01)

**Social QoL:**

+ 8.0 % (p<.01)

**Environmental QoL:**

+ 7.8 % (p<.01)

### RESEARCH QUESTIONS AND FINDINGS

1. **Did Group Assignment Impact Quality of Life?**
   - **No.** Change in Quality of Life from baseline to 3 months was not different between IOP and OP groups.

### Table 2. Condition x Time interactions in GEE models for each QoL domain.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Physical QoL</th>
<th>Psychological QoL</th>
<th>Social QoL</th>
<th>Environmental QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>χ² (1) = 0.16</td>
<td>χ² (1) = 1.1</td>
<td>χ² (1) = 0.55</td>
<td>χ² (1) = 0.01</td>
<td></td>
</tr>
<tr>
<td>ρ = .69</td>
<td>ρ = .29</td>
<td>ρ = .46</td>
<td>ρ = .94</td>
<td></td>
</tr>
</tbody>
</table>

2. **Did Participants’ Quality of Life Improve at 3 months?**
   - **Yes.** Participants reported significant increases in all Quality of Life domain scores.

### Table 3. Change in QoL from baseline to 3 month follow-up.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Physical QoL</th>
<th>Psychological QoL</th>
<th>Social QoL</th>
<th>Environmental QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ 11.7 % (p&lt;.01)</td>
<td>+ 10.8 % (p&lt;.01)</td>
<td>+ 8.0 % (p&lt;.01)</td>
<td>+ 7.8 % (p&lt;.01)</td>
<td></td>
</tr>
</tbody>
</table>

3. **Did Stopping Buprenorphine Treatment Degrade Quality of Life?**
   - **Yes, mostly.** Those who stopped taking buprenorphine had lower Quality of Life in Psychological and Environmental domains than those who were still in treatment at 3 month follow-up.

**DISCUSSION**

- Buprenorphine treatment rapidly enhances Quality of Life among opioid-dependent African Americans.
  - Participants reported improvement in all of the Quality of Life domains examined.

- For most domains, gains in Quality of Life were driven by those who remained in treatment. Discontinuation of treatment by 3 months was associated with lower Quality of Life for two out of four domains.

- On an intent-to-treat basis, there was no discernable advantage to IOP level treatment as compared to OP level treatment.

- While participants in IOP received significantly more counseling than OP participants (p<.01), the qualitative difference was small.
  - Weekly hours of counseling received per active treatment week = 4.2 for OP vs. 6.0 for IOP.
  - This study examined treatment as delivered in actual clinical practice.

- Future research will examine the persistence of these Quality of Life gains over a longer period of time.
443 eligible patients entering buprenorphine treatment

95 Declined to participate
(92 passive; 3 active)

3 excluded due to comprehension difficulties

345 Randomized

175 randomized to receive OP
(11 excluded from discontinued site)
(1 excluded due to court-mandated IOP)
(1 excluded as cross-clinic double-enrollment)
(1 voluntarily withdrew)
(6 excluded because not African American)

170 randomized to receive IOP
(10 excluded from discontinued site)
(1 excluded as erroneous double-enrollment)
(1 excluded because not African American)
(1 excluded as clinic error – not regular admission)
(13 excluded because not African American)

155 African Americans randomized to OP
145 interviewed at 3 months (95.5%)
145 Analyzed

145 African Americans randomized to IOP
138 interviewed at 3 months (95.2%)
145 Analyzed

Figure 1. Number of endorsed DSM-IV symptoms: Opioid Dependence

Figure 2. Number of endorsed DSM-IV symptoms: Cocaine Dependence