

Sequential multiple assignment randomized trial (SMART) adaptive studies for SUD

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Problems in SUD treatment

- High dropout rate
 - PTs' mixed reactions to “standard care” in the treatment system:
 - Behavioral interventions
 - Group counseling
 - 12-step model (i.e., AA approach)
 - Currently, treatment seekers with substance use disorders (SUD) really do not have many TX options
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Adaptive Treatment Study

□ Research Questions

- Does offering patients who do not engage in treatment a choice of other interventions improve outcomes?
 - Does offering patients who engage but then drop out a choice of other interventions improve outcomes?
 - Does a second attempt to offer TX choice to non-engagers improve outcomes?
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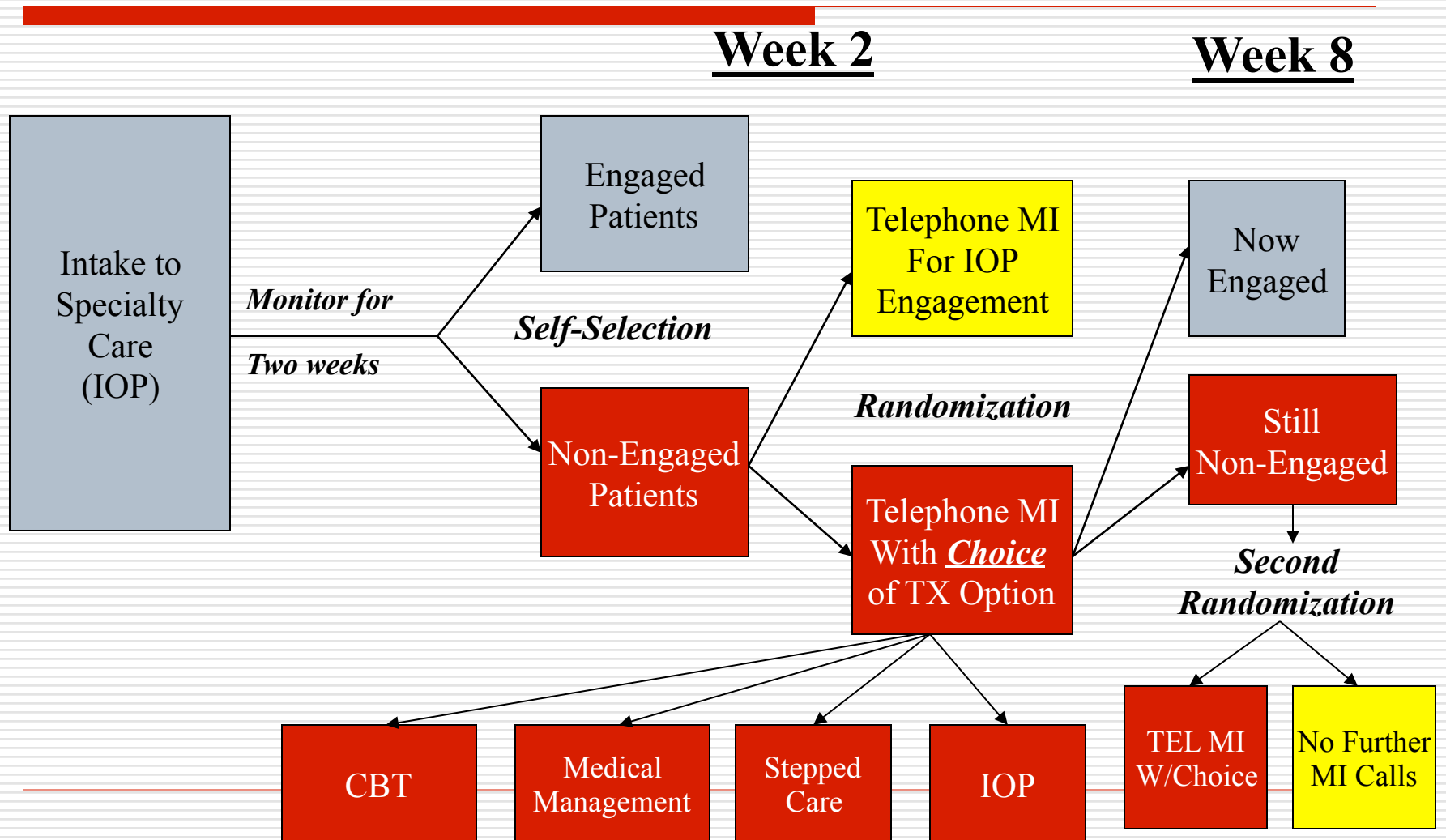
Tailoring Variable

- We are tailoring on ***IOP attendance*** (rather than substance use)
 - Definition of “disengaged” was derived through an expert consensus process
 - At 2 weeks: failure to attend any treatment in the second week following intake
 - During weeks 3-7: failure to attend any IOP sessions for two consecutive weeks
 - At 8 weeks: failure to attend any IOP sessions in prior two weeks
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Treatment Sites and Patients

- Participants recruited from IOPs in publicly funded and VA programs
 - Participants enrolled at intake
 - Two studies:
 - Cocaine dependent (N=300), 80% with alcohol dependence
 - Alcohol dependent (N=200), 40% with cocaine dependence
 - Typical participant: African-American male, around 40yo
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Adaptive Protocol With Patient Choice



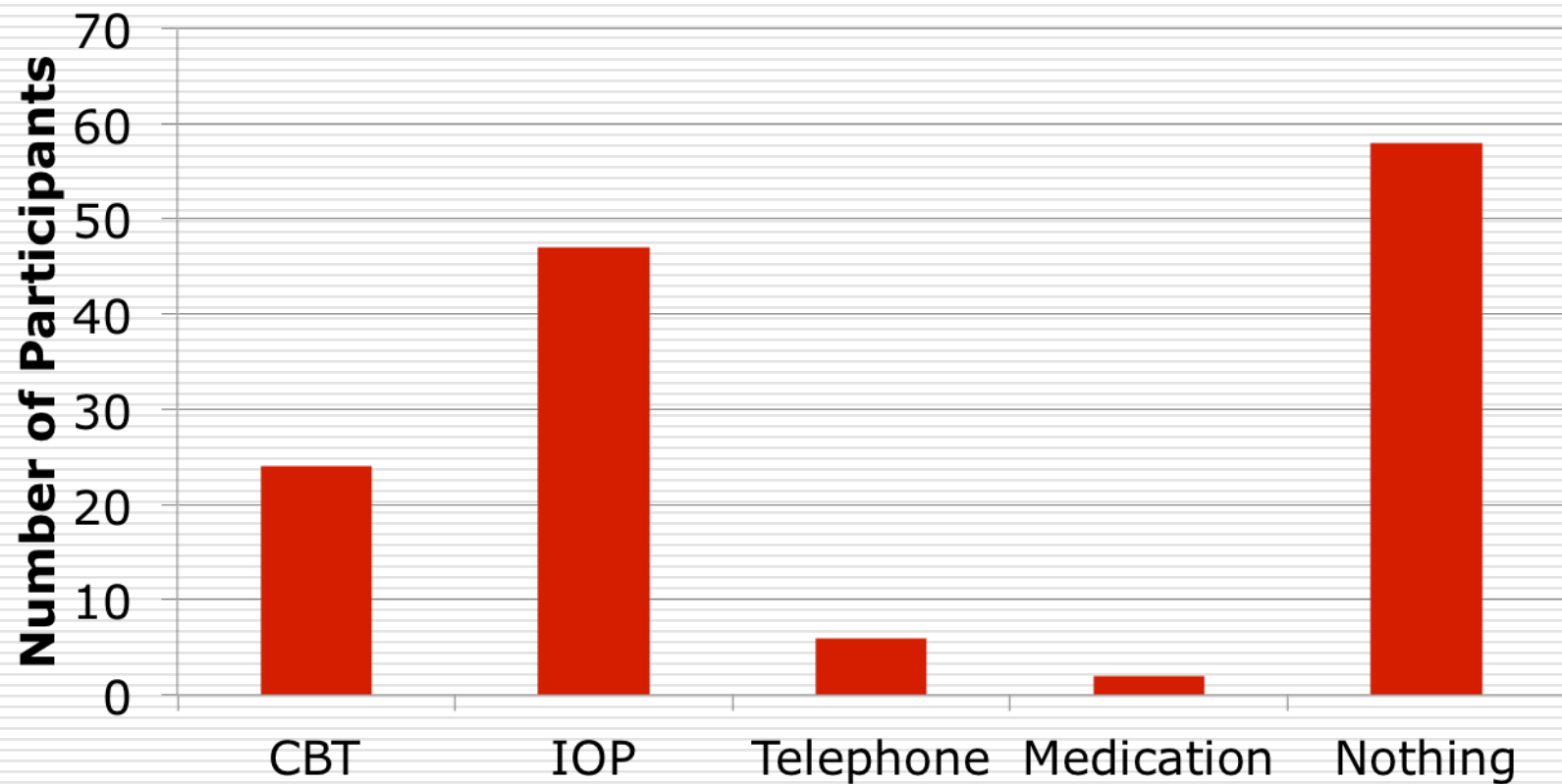
Monthly Outcome Measures

- Alcohol Use (for alcohol dependent Pts)
 - Any use and any heavy use
 - Frequency of any and heavy use
 - Cocaine Use (for cocaine dependent Pts)
 - Any use
 - Frequency of use
 - Urine toxicology
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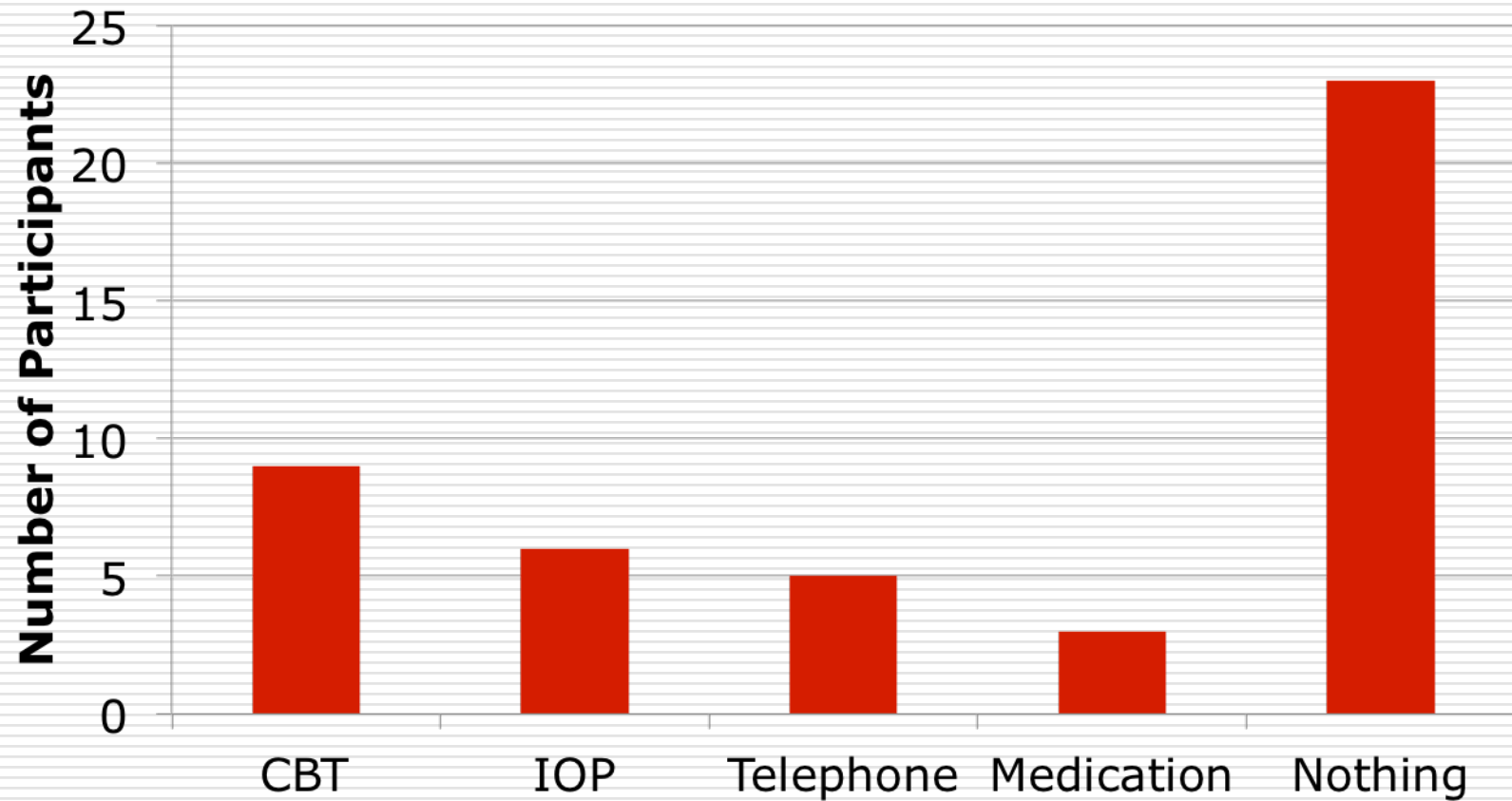
Study Participation

- Engaged/Disengaged at Week 2:
 - Study 1– 188 (63%) / 112 (37%) of 300
 - Study 2– 123 (62%) / 77 (38%) of 200
 - Disengaged Weeks 3-7:
 - Study 1—43 (23%) of 188 engaged at W2
 - Study 2—24 (20%) of 123 engaged at W2
 - Still disengaged at Week 8:
 - Study 1—66 (59%) of 112 disengaged W2
 - Study 2—43 (56%) of 77 disengaged W2
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What non-engaged MI-PC PTs select in weeks 2-7:



What non-engaged MI-PC PTs select at week 8: (at re-randomization)

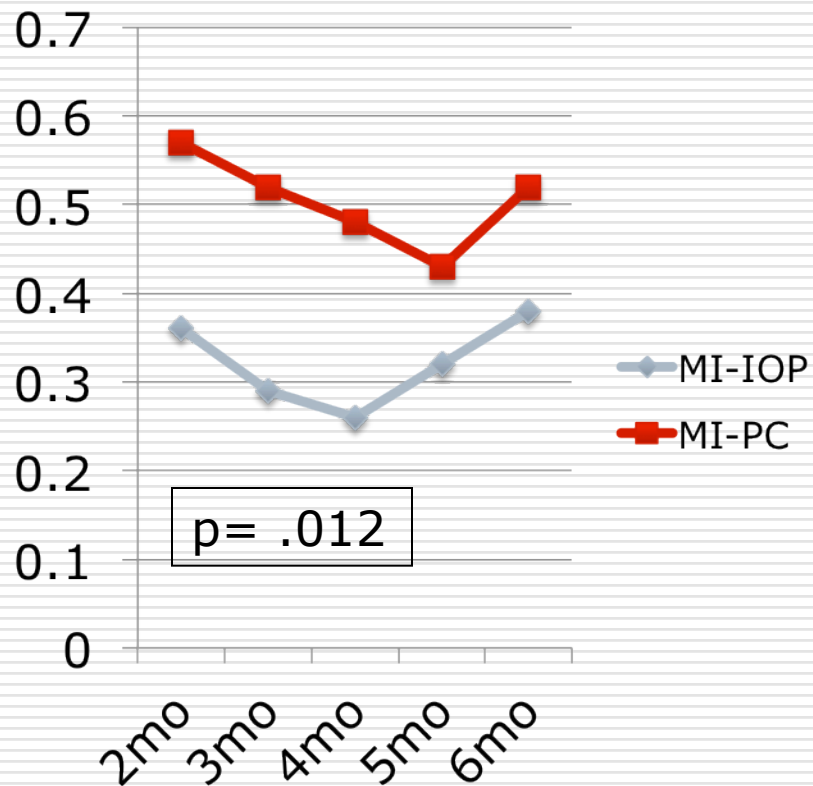


Main Effects Analyses

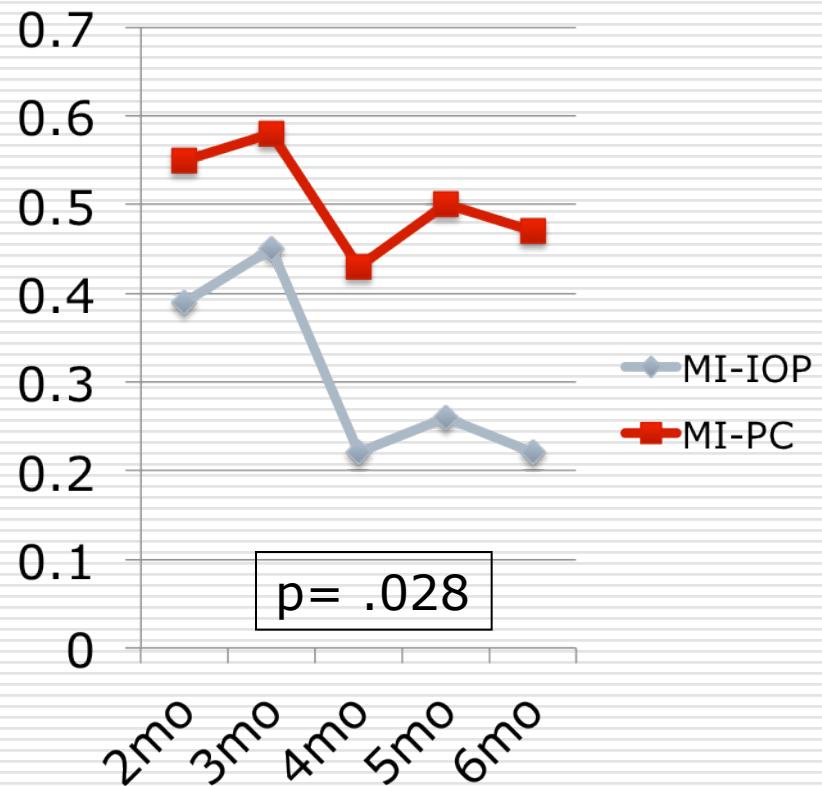
Alcohol Use in Patients
Disengaged at 2 weeks

Any Alcohol Use in Month

Study 1

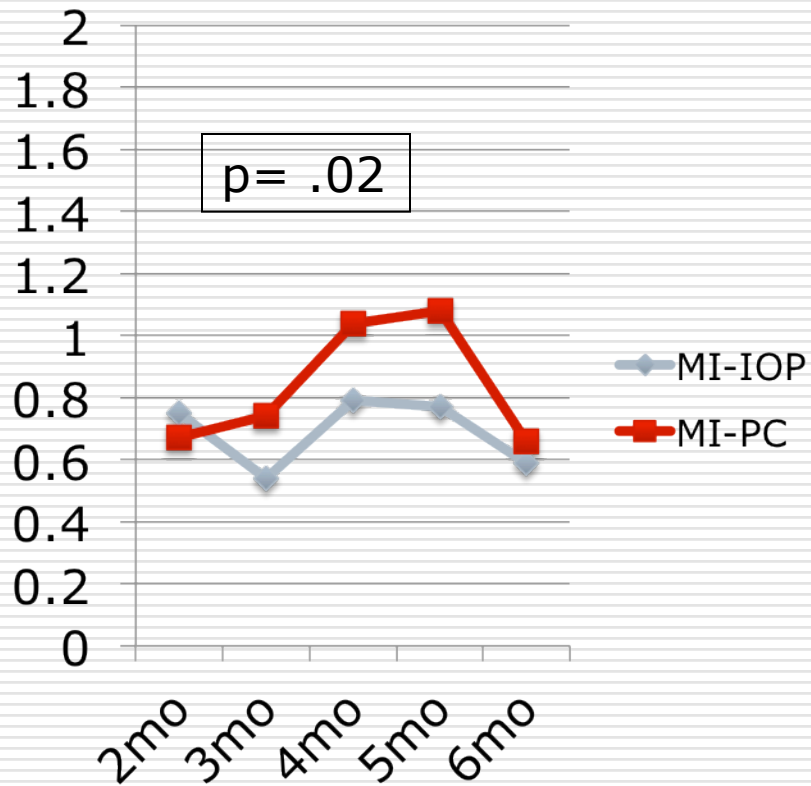


Study 2

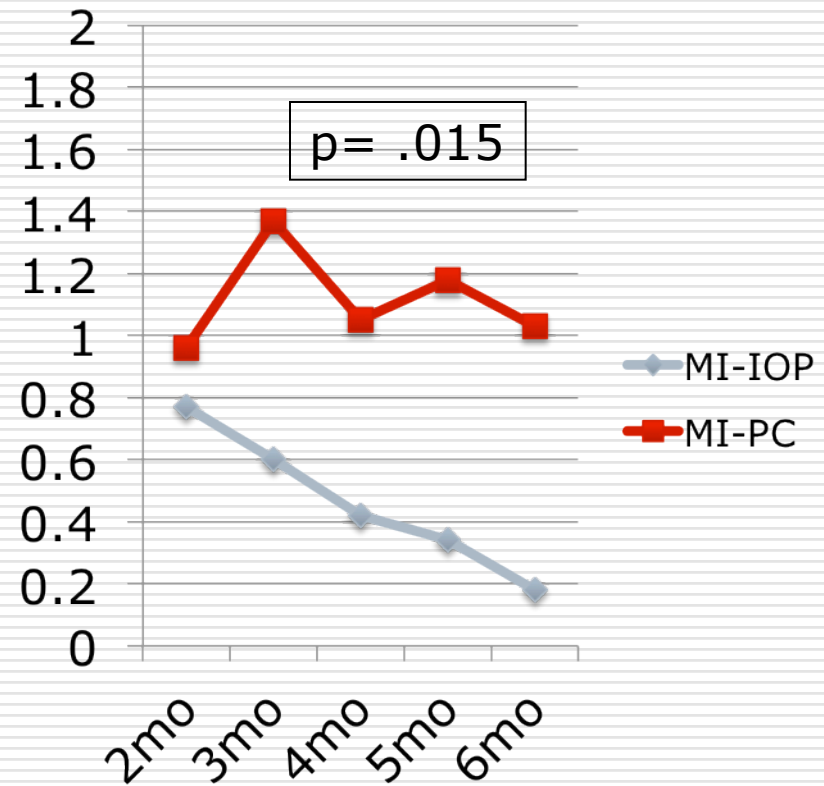


Days of Alcohol Use per Week

Study 1



Study 2



Alcohol outcomes in combined sample (161 of 428 alc dep)

- Any drinking:
 - OR= 0.40, p= .0007
- Any heavy drinking
 - OR= 0.33, p= .001
- Frequency of drinking
 - B= -1.08, p= .009
- Frequency of heavy drinking
 - B= -1.09, p= .003

MI-PC= 0, MI-IOP= 1

Main Effects Analyses

Alcohol Use in Patients
Disengaged between
weeks 3 and 7

Disengaged in weeks 3-7 in combined sample (N=73)

- Any alcohol use
 - OR= 0.54, p= .16
- Any heavy alcohol use
 - OR= 0.67, p= .36
- Frequency of use
 - B= -0.84, p= .23
- Frequency of heavy use
 - B=-1.03, p= .10

MI-PC= 0, MI-IOP= 1

Main Effects Analyses

Alcohol Use in Patients
Disengaged at both
2 and 8 weeks

Disengaged at weeks 2 and 8 in combined sample (N=86)

- Any alcohol use
 - OR= 1.12, p= .79
- Any heavy alcohol use
 - OR= 1.43, p= .45
- Frequency of use
 - B= -0.34, p= .58
- Frequency of heavy use
 - B= 0.02, p= .97

MI-PC= 1, no further outreach=0

Main Effects Analyses

Cocaine Use Outcomes

Cocaine use (N= 409)

- PTs disengaged at w2 (N=159):
 - NS (P values .13 to .86)
 - PTs disengaged in w3-7 (N=69):
 - NS (p values .16 to .74)
 - (results in direction of IOP better than PC)
 - PTs disengaged w2 and w8 (N=84):
 - NS (p values .14 to .42)
 - (results in direction of NFO better than PC)
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Conclusions

- ❑ Providing substance dependent patients who fail to engage in IOP a choice of other treatment options does not improve alcohol or cocaine use outcomes
 - ❑ In fact, outreach *without a choice of other treatments* leads to better alcohol use outcomes in those who do not engage in IOP initially
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Conclusions

- Also, no advantage to providing a choice of interventions to patients who engage initially but then drop out
 - Finally, providing further outreach with a choice of interventions to those not engaged at 2 and 8 weeks did not improve substance use outcomes compared to no further outreach
 - Possible exception: patients with past rather than current dependence at intake
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Encouraging results

- ❑ It is possible to successfully implement a SMART project in SUD patients
 - ❑ Use of telephone MI made it possible to at least reach most patients after 1st and 2nd randomization, even though they were not engaged in treatment.
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Challenges in Adaptive Treatment for Substance Dependence

- ❑ PTs who are doing badly are hard to reach and are often unwilling to participate further in treatment of any sort
 - ❑ Mechanisms of action in behavioral treatment options may not be sufficiently different that PT doing poorly in one will respond to another
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Collaborators

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- Kevin Lynch
- Tom Ten Have
- Debbie Van Horn
- Michelle Drapkin

□ Consultants

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