

Medication-Assisted Treatment Commission
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The evidence-based role for counseling with opioid use disorder pharmacotherapy

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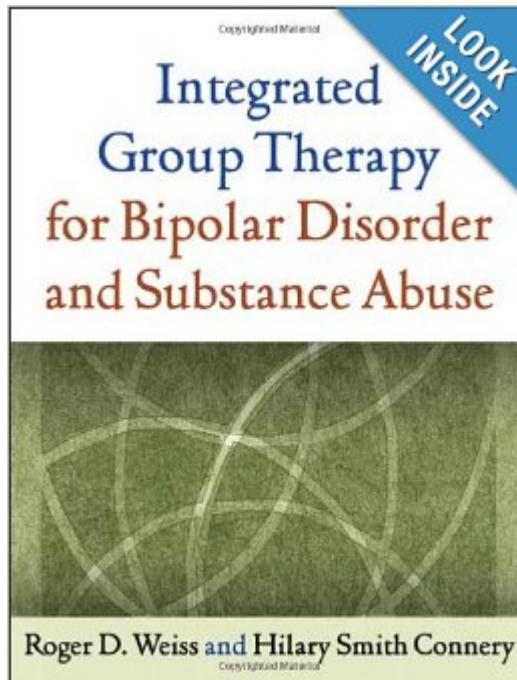
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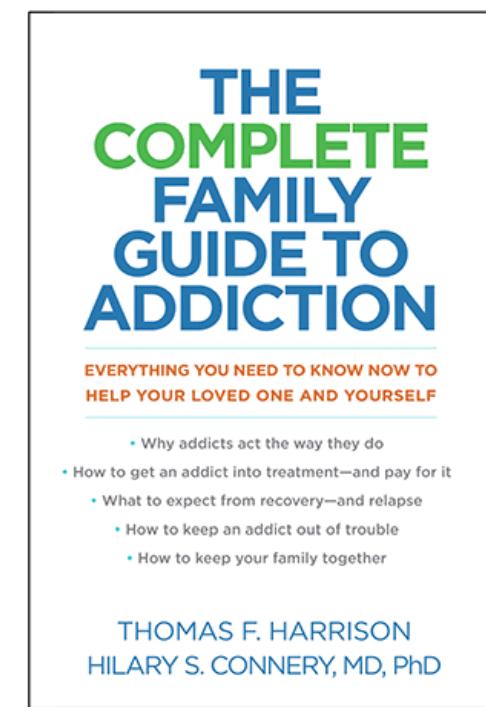
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COUNSELING DEFINITIONS IN DRUG USE DISORDERS



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Counseling definitions

1. **Medical counseling:** brief education, medication adherence, goal-setting, often encourages 12-step participation. Usually \leq 20 mins, individual only.

Fiellin et al., 2002, 2006

2. **Drug counseling:** gold-standard for SUD includes skills training on recognition of triggers, craving management, coping with guilt/shame, refusal skills, relationship management, emotional coping, and 12-step participation. Disease model + spiritual recovery philosophy. 45-60 mins. Abstinence-based treatment, individual and group.

Mercer & Woody, 1992, 1999; Daley, Mercer & Carpenter, 1992, 2002



Counseling definitions

3. **Cognitive behavioral therapy for relapse prevention:**
adapted from CBT for depression, individual, 45-60 min.
Functional analysis of drug use
(antecedents/consequences) + cognitive restructuring and
skills management training.

Carroll, 1998

4. **Contingency Management:** operant reinforcement of treatment adherent behaviors and goal achievement by timely provision of incentives (take-home doses, prize draws, vouchers). Layered over structured treatment delivery (individual or group).

Stitzer et al., 1986, 1992; Preston et al. 1999



Commonly used but....

Motivational Enhancement Therapy: built on motivational interviewing principles and philosophy to strategically facilitate positive behavior change by affirming self-efficacy and evoking natural patient incentives and resourcefulness. Individual in both brief (5-15 min.) and extended (45-60 min) sessions. Developed for alcohol use disorder, not drug use disorders.

Miller, Zweben, DiClemente, & Rychtarik, 1999

Family Therapies: diverse partner-based or parent-based enhancement of treatment adherence, such as Adolescent Community Reinforcement Approach (A-CRA)

Dennis et al., 2004



Uncommonly used....

Twelve-Step Facilitation Therapy: manualized therapy focusing on optimizing a patient's capacity to participate optimally in 12-step mutual help programs. Developed for alcohol use disorder, not drug use disorders, it focuses on moving through steps 1-3 and each individual session ends with assignment of recovery tasks oriented toward active 12-step participation. This structured approach is quite different than the usual encouragement and discussion of 12-step adjuncts that is delivered in clinical treatment settings, but may be closer to what is delivered in “drug-free” community recovery programs.

Nowinski, Baker & Carroll, 1999

Federal definitions (OTP)



Behavioral health services means any non-pharmacological intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered interventions (e.g., cognitive behavior therapy or insight oriented psychotherapy) delivered in person, interventions delivered remotely via telemedicine shown in clinical trials to facilitate medication-assisted treatment (MAT) outcomes, or non-professional interventions.

Section 42 Code of Federal Regulations 8.2



Federal definitions (OTP)

Medication-Assisted Treatment (MAT) means the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder.

Interim maintenance treatment means maintenance treatment provided in an opioid treatment program in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment. (not more than 120 days)



Fact 1: no OUD maintenance medication has been studied *without* counseling



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Methadone maintenance



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Methadone maintenance



Counseling component foundational to service delivery

McLellan et al., 1993; Hagman, 1994

Pharmacotherapy + drug counseling + behavioral contingency management, +/- specialized psychotherapies

Woody, 2003; Carroll & Onken, 2005

Interim medication management: closest study to “no counseling”: pharmacotherapy observed daily + limited contingency management + emergency counseling only, longest duration 120 days. IM = standard MMT for opioid outcomes; limited by standard MMT here received minimal counseling (once q 2 wks, 40-50 caseload). Schwartz et al., 2011

Agonist maintenance for OUD

Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence, WHO, 2009, section 3.8

“Treatment of opioid dependence is a set of pharmacological and psychosocial interventions aimed at:

- reducing or ceasing opioid use
- preventing future harms associated with opioid use
- improving quality of life and well-being of the opioid-dependent patient.”

Agonist maintenance for OUD



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Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence, WHO, 2009, section 3.8

“...it can provide access to physical and psychiatric care and social assistance, and provide for the needs of the patient's family as well as those of the patient.

In most cases, treatment will be required in the long term or even throughout life. The aim of treatment services in such instances is not only to reduce or stop opioid use, but also to improve health and social functioning, and to help patients avoid some of the more serious consequences of drug use.”



Buprenorphine maintenance



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Buprenorphine maintenance

Counseling component for the first 8-site double-blind placebo-controlled RCT of office-based care (4 weeks):

1. Daily dosing M-F, weekend take-home doses
2. Urine tox M, W, F
3. All the subjects received counseling regarding human immunodeficiency virus infection and up to one hour of individualized counseling per week. Emergency counseling (e.g., after a relapse) and referrals (e.g., to community legal aid programs) could be provided, but no other counseling or services (e.g., regarding family or employment issues) were offered.



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Buprenorphine maintenance

Counseling component for the first PCP 24-week RCT of office-based care using medical counseling vs. enhanced counseling, N=166:

1. Once/wk or 3x/wk dosing for medical, 3x/wk dosing enhanced
2. Urine tox weekly
3. “Sessions covered recent drug use or efforts to achieve or maintain abstinence, attendance in self-help groups, support for efforts to reduce drug use or remain abstinent, advice for the achievement or maintenance of abstinence, and the results of analysis of weekly urine specimens.”

Fiellin et al., 2006

“Standard Medical Management”

- 20 mins weekly medical counseling - manualized
- Urine toxicology review
- Weekly dosing yoked with visit
- Medication adherence and side effects
- Opioid withdrawal assessment (COWS)
- Opioid reduction goals progress
- Opioid craving
- Encourage 12-step participation
- Health education re: injection use, HIV/HCV/HBV, overdose risk with polysubstance use

“Standard Medical Management”

- Lifestyle changes to avoid risk situations and triggers
- Assessment of pain when appropriate
- Referral to vocational, housing, social and legal services as needed
- “SMM should not be expected... to provide adequate treatment for patients with significant comorbid psychiatric disorders... In addition, it is expected that social services such as social workers, domestic violence services and housing agencies will be available to provide many services that go beyond the scope of SMM.”

Buprenorphine maintenance



Counseling component for multi-site CTN trials:

1. Detox versus 12-week maintenance in adolescents/youth:
 - weekly MD visits with dosing and urine tox review
 - weekly individual + group drug counseling

Woody et al., 2008

2. Buprenorphine for Rx OUD: medical counseling +/- individual drug counseling, phase 1 detox/phase 2 maintenance
 - weekly MD visits w/ dosing, urine tox review, pill counts
 - randomized to added IDC weekly
- Weiss et al., 2011



Buprenorphine maintenance

In all these trials, maintenance on buprenorphine the main driver of good clinical outcomes, and more intensive drug counseling specific to OUD did not add benefit (*secondary analysis suggested benefit for h/o heroin use in Rx OUD if adherent)

Carroll & Weiss, review, 2017:

- 4 of 8 RCT show efficacy with medical counseling
- 4 of 8 show benefit with greater intensity counseling, especially contingency management
- Lower quality medical counseling + drug counseling?
- High drop-out problematic in all cases



ER-naltrexone maintenance



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ER-naltrexone maintenance

Counseling component for the first multisite, double-blind placebo-controlled RCT of office-based care (24 weeks):

1. Once monthly injection
2. Urine tox weekly
3. Every other week individual drug counseling for OUD:

“Psychologists or psychiatrists who were trained in individual drug counselling reviewed patients’ substance use, recovery efforts, functioning, and adverse events, and provided support and advice to patients.”

Krupitsky et al., 2011



ER-naltrexone maintenance

Counseling component for multisite, effectiveness RCT of office-based ER-NTX versus SL buprenorphine (24 weeks):

1. Weekly urine tox, opioid cravings, assessment of psychiatric as well as substance use
2. “Medical management focused on provider–patient rapport, medication adherence and side-effects, non-study opioid abstinence, and promoted other psychosocial treatment. Additional voluntary ancillary psychosocial counselling was recommended and available at all sites.”

Lee et al., 2018



**Fact 2: OUD has poor retention
medical +/- drug counseling +/- case
management**



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Drop out in OUD maintenance

- Average *minimum* 30% drop-out within first month, especially if toxicology shows opioid use
- Transitional age youth have higher drop-out rates
- No better than 50% average retention beyond 6 months
- Opioid withdrawal states are not amenable to counseling
- Perhaps the reason contingency management is so effective
- Little research on impact of Recovery Coaches

Incentives for retention will prevent dropout, overdose, and OUD sequelae



CONCLUSIONS

Medical counseling proven in studies is superior in quality and frequency to what is commonly available in community settings

Keeping patients in treatment and adherent with OUD pharmacotherapy appears to drive positive outcomes

Barriers to long-acting buprenorphine should be addressed

Psychological services ?? preferentially allocated to those with greater readiness for change, and pregnant women ??



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Thank you!

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