

Balancing Treatment Fidelity with Feasibility and Acceptance by End Users

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#DementiaCareSummit



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Experience with the NYUCI in Research and Translation

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Issues and Questions

- How to assure fidelity to evidence-based interventions
- Is it enough to provide the “essence” of an evidence-based intervention?
- How do you know what the essence is?
- What happens if you change the intervention too much? Will you produce the benefits demonstrated by the original evidence-based intervention?
- What happens if you provide too little?
- How can we make a psychosocial intervention appealing to consumers?
- What do payers want to support? Should an intervention be changed to ensure that payers will support it?



An Example: The NYU Caregiver Intervention (NYUCI) in Research and in the Community

Initial Research and Efforts to Make an Evidence-based Intervention Widely Available to Those who Might Benefit



The NYU Caregiver Intervention (NYUCI)

- A multi-component intervention that provides counseling, support and education
- Originally designed for spouses or partners living with the person with dementia
- Individualized to the needs of each family
- Emphasizes support for the primary family caregiver
- Includes the caregiver and other family members
- Available when needed and as long as needed
- Geared to the stage of dementia and the strengths and limitations of the person with dementia and the family caregivers.

Design of the NYU Caregiver Intervention

- Comprehensive intake assessment and regular follow-up assessments
- Scheduled individual and family counseling sessions within four months of enrollment
 - One individual counseling session
 - 4 family counseling sessions
 - A second individual counseling session
- Recommendation for continuous participation in a support group
- Ad hoc counseling - telephone consultation on request of caregiver or family member over the entire course of the disease.

Results of Original RCT of NYUCI (1987-2010; n=406 spouse caregivers)

- *Improved support* for caregiver for at least 5 years
- *Reduced caregiver depression* for at least 3 years
- *Reduced caregiver stress reaction* to behavior of person with dementia for at least 4 years
- *Improved caregiver self rated health* for at least 4 years
- *Postponed nursing home placement of person with dementia* 557 days
- *Reduced caregiver depressive symptoms and burden during the transition to a nursing home*
- *Effects persist through bereavement*
- **Moderator of all other outcomes is social support**
- Note: Fewer than 5% dropped out while the person with dementia was still living at home.

NYUCI Translations and Additional RCTs

Translations					
<u>Years</u>	<u>Place</u>	<u>Screened</u>	<u>Enrolled</u>	<u>Dropped</u>	<u>Complete*</u>
5.5	AoA Minnesota	248	228	37	123
3	AoA California	200	140	29	111
3	AoA Georgia	400	158	59	63
3	AoA Florida	200	173	16	103
3	AoA Utah	150	109	16	93
3	AoA Wisconsin	131	74	17	43
2	VA Bedford MA	81	13	3	10
2	VA Manhattan NY	61	4	1	3
1	EmblemHealth	71	15	6	1
1	U. Queensland, Australia	?	12	2	1
	Total	1542+	926	186	551
New RCTs					
<u>Years</u>	<u>Place</u>	<u>Screened</u>	<u>Enrolled</u>	<u>Dropped</u>	<u>Complete*</u>
3	US, UK and Australia	unknown	158	32	135
3	Washington Heights	282	139	23	118
2	Israel	137	101	21	80
5	Minnesota NYUCI-AC	126	107	1	106
0	Paris, France	0	0	0	0
	Total	545+	505	77	439

* Complete means at least one follow-up assessment completed

Trained Providers are Necessary, but not Sufficient for Fidelity to an Evidence-based Intervention

- We wrote a book describing the intervention in detail
- We conducted in person training of new providers
 - 1.5 days
 - Two educators – M. Mittelman and C. Epstein
 - We traveled to sites of providers.
- Now evidence-based online training with certification is available
 - Can be viewed any time, with no travel required
 - 10 hours minimum, plus passing grade on an online exam
 - Information, videos of role play and real cases with discussion



What Happens when the Developers don't Provide the Training?

- Minnesota AoA translation
 - Originally, we trained the providers
 - A decision was made to have local people, not necessarily trained by us, do the training
 - Analysis showed that outcomes were better for those trained by us
- Israeli NYUCI (Lituf) randomized controlled trial
 - Community providers decided not to do detailed follow-up evaluations of control group caregivers
 - EMDA decided to do what they call the NYUCI all over Israel, with providers with no training by us. What are they doing?



Changing the Intervention too Much The Dutch FAME Study

- Intervention: 4 family meetings over a 12 months period. **Frequency of dose changed**
- Eligibility: Any family caregiver of a person with dementia living in the community
Eligibility for original study was spouse caregivers living with person with dementia.
- RCT: 192 caregivers
 - Treatment group: NYUCI plus services provided to control group
 - Control group: Intensive routine care such as case management and support groups
Assumption that family meetings would have incrementally significant effect
 - Outcomes measured every 3 months **Our first follow-up was after all 6 counseling sessions**
- Outcomes of interest: Major depressive disorder, anxiety disorder **Different outcomes from original study**
- Results
 - 44/96 completed one individual counseling session plus 3 or 4 family meetings within 12 months **Poor adherence compared to NYUCI**
 - No difference was found between the intervention and control groups on outcomes measured.



Is it Okay to Provide Less than the Full Intervention? What Happens if More is Provided?

- Minnesota translation AoA-funded from 2008-2013
- 228 spouse caregivers enrolled
 - More than ¾ completed intervention
 - More than half completed follow-up assessment
- Similar effects on depression and stress to original study
- However
 - Many caregivers received fewer than 6 counseling sessions
 - Mean time to nursing home placement for those receiving four to six sessions was 436 days compared to 183.6 days for those receiving 1 to 3 sessions
- 3 Country Study
 - Counselor in Australia provided more than 6 sessions. No effect on outcomes



Dichotomy between what Consumers Want and What Research Suggests is Best for Them

Consumer Issues

- Most caregivers would like an effective medication for the person with dementia
- Consumers don't see the value of an assessment
- Minnesota AoA-funded study indicated that most spouse caregivers were reluctant to involve their family members. They didn't want family counseling.

What we Know will Help

- Psychosocial interventions
- We can provide more tailored treatment if we do a good assessment
- When persuaded, they said that family counseling was the most helpful part of the intervention
 - In our current service program, funded by New York State, we find that it takes more than 1 individual session to convince caregivers to include other family members.

What Does the Payer Want? Economically Viable Interventions, at Worst Cost-neutral

- Model of cost savings from postponement of nursing home placement was more persuasive than effects on caregiver health and well-being
- New York State provided \$75 million to the Department of Health for family support services throughout the state based on the results of a cost study of the NYUCI
 - The family support programs are informed by the services that comprise the NYUCI
 - Number of people served is an important metric
 - Evaluation of effect will be difficult without a control group, but is essential to expand the evidence base
- Reducing cost of intervention
 - Issue: Travel time for counselors vastly increases cost and caregivers are reluctant or unable to travel to services
 - Response: ENYUCI and the NYU Family Support Program are available online, which will substantially reduce cost and expand the number of caregivers served.

Recommendation: Market Research is Essential to Enhancing Feasibility and Acceptance of Evidence-based Interventions by Stakeholders

- **How to appeal to consumers**
 - How to create awareness
 - Understand how and why caregivers seek help
 - Understand why caregivers choose a service
 - Potential consumers need to be persuaded that a psychosocial intervention is currently the best available treatment.
- **How to get buy-in from providers**
 - Dissemination of information about evidence-based interventions to providers in user friendly format
 - Widely available training and certification for providers
 - Forum for providers to share experiences of success and barriers
- **How to convince payers to fund evidence-based interventions**
 - How to reach decision-makers
 - What mandates do they have that we can help them fulfill?
- **How to get stakeholders to work together.**