

Evidence Based Behavioral Medicine: Taking the Context into Account

SBM 2009, Montreal

Speakers: Arja Aro
Bonnie Spring
Joost Dekker

Discussant: Neil Schneiderman

Three speakers today emphasized

- Importance of Evidence Based Tx**
- Consideration of the Context**

**These are important in
randomized clinical trials, health
promotion campaigns and clinical
practice**

Evidence Based Treatment and Consideration of Context in Randomized Clinical Trials

The latest meta-analysis of CVD patients indicated that mortality benefits due to psychosocial treatment apply to men but not to women

(Linden et al., *Eur. Heart Journal*, 2007)

**ENRICHD (2003) randomized
2481 post-MI men and women
into intervention versus usual
care**

**–Psychosocial intervention did
not decrease all-cause mortality
or recurrent nonfatal MI**

Because ENRICHD had women and men, majority and ethnic minority post-MI patients, it was possible to conduct a secondary analysis on sex by ethnicity subgroups

This secondary analysis indicated that the intervention decreased incidence of death and nonfatal MI in white men but not other subgroups

White Men

| | Hazard Ratio | 95% Confidence Interval | Long- rank p-value |
|------------------------|-----------------|-------------------------------|--------------------------|
| All death or NF MI | 0.80 | [0.61-1.05] | .10 |
| Cardiac death or NF MI | 0.63 | [0.46-0.87] | .00 |
| Cardiac death | 0.63 | [0.40-0.99] | .05 |
| Nonfatal MI | 0.61 | [0.40-0.92] | .02 |

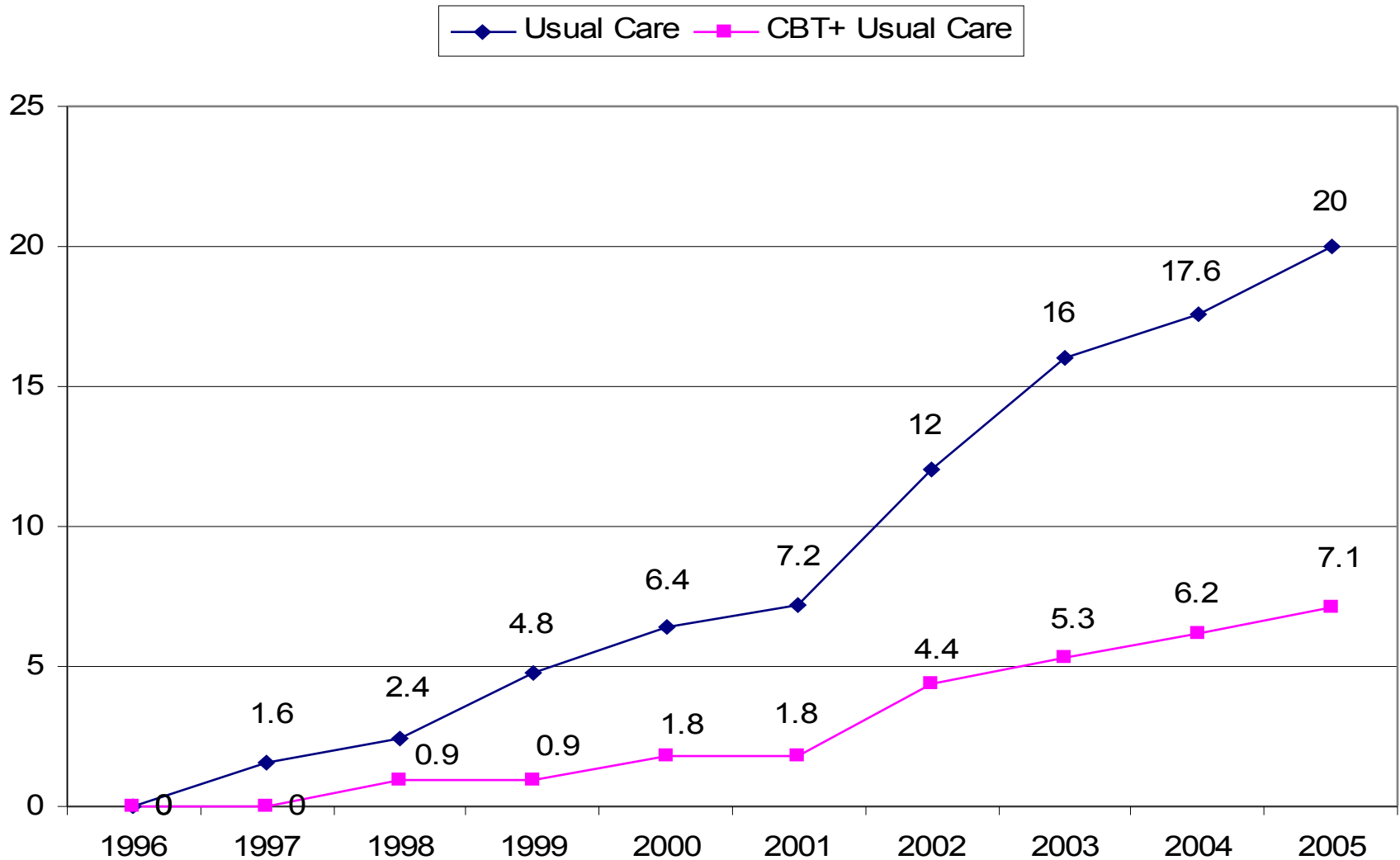
(Schneiderman et al., 2004, *Psychosomatic Medicine*)

In the Stockholm Women's Intervention Trial for Coronary Heart Disease (SWITCHD), 237 women after acute coronary syndrome received either: a) 20 sessions, each 2.5 hours of group-based CBSM; or (b) Usual Care (Orth-Gomér et al., 2009)

At the end of 7 years there was a 67% decrease in mortality in women in the intervention group compared to controls (OR=0.33, 95% CI, 0.15-0.74, p = 0.007)

Cognitive Behavioral Therapy (CBT) in Women with CVD

All Cause Mortality



SWITCHD and ENRICHD differed from each other in important ways

–For example, SWITCHD used same sex groups whereas ENRICHD used mixed gender groups

Anecdotal evidence from ENRICHD indicated women were less likely than men to interact in group sessions, and were reluctant to confront male participants

–The context was important

– In patients with severe CVD it may be better to conduct CBSM in same sex groups

All three of our speakers emphasized the need for tailoring our interventions to the context

-In our CBSM studies conducted on poor ethnic minority women living with HIV/AIDS, adherence to homework assignments was poor

However, the women were eager to come in a half hour early and do the assignment jointly with another participant.

Ethnic minority cultures often foster the notion of having people come together to work collaboratively on a problem.

**Large scale multi-center
epidemiological studies help
us to understand the cultural
context for interventions**

Hispanic Community Health Study is examining acculturation, cultural norms, protective health factors, risk factors and health care utilization in 16,000 U.S. Hispanic/Latinos as a function of ethnic subgroups.

–This can help us tailor intervention research

Both Bonnie and Joost have emphasized that within the practice of Evidence Based Treatment there is a need for shared decision making between patient and therapist.

The Diabetes Prevention Project (2002) randomly assigned 3234 men and women at high risk for Type 2 diabetes for 2.8 years to:

- Placebo**
- Metformin**
- Intensive Lifestyle Modification**

Diabetes Reduction Incidence

–58% by lifestyle intervention

–31% by metformin

Both tx significantly differed from placebo ($p < 0.001$ for each comparison)

For patients unlikely to manage a rigorous lifestyle intervention, metformin may be an appropriate alternative treatment

– This can be supplemented if feasible with modest increases in physical activity and some changes in diet.

Arja showed how in health promotion, taking the context into account ranges from changing policy to engaging local and regional resources

– Her outstanding example was the North Karelia Project, which changed all of our views about how health promotion research could be implemented

Project ASSIST

**US National Cancer Institute of
NIH funded an 8 year
demonstration project to help 17
state health departments
implement tobacco control plans**

Study compared smoking prevalence between 17-ASSIST states and 33 non-ASSIST states

ASSIST Strategies

- **Promote smoke-free environments**
- **Counter tobacco advertising and promotion**
- **Limit youth access to tobacco**
 - **Restrict placement of cigarette vending machines**
- **Raise excise taxes on tobacco**

Results

ASSIST states had a greater decrease in adult smoking prevalence than non-ASSIST states, with an adjusted difference of -0.63% (p=.049)

CONCLUSION

- **Procedures are in place for assessing translations of efficacy into effectiveness**
- **More clinical trials are needed to examine how moderators influence health interventions**

CONCLUSION

- **The literature suggests that tx approaches can combine patient preference with research evidence**
- **Research suggests that health promotion interventions can take the context into account including changing government policy and engaging resources**