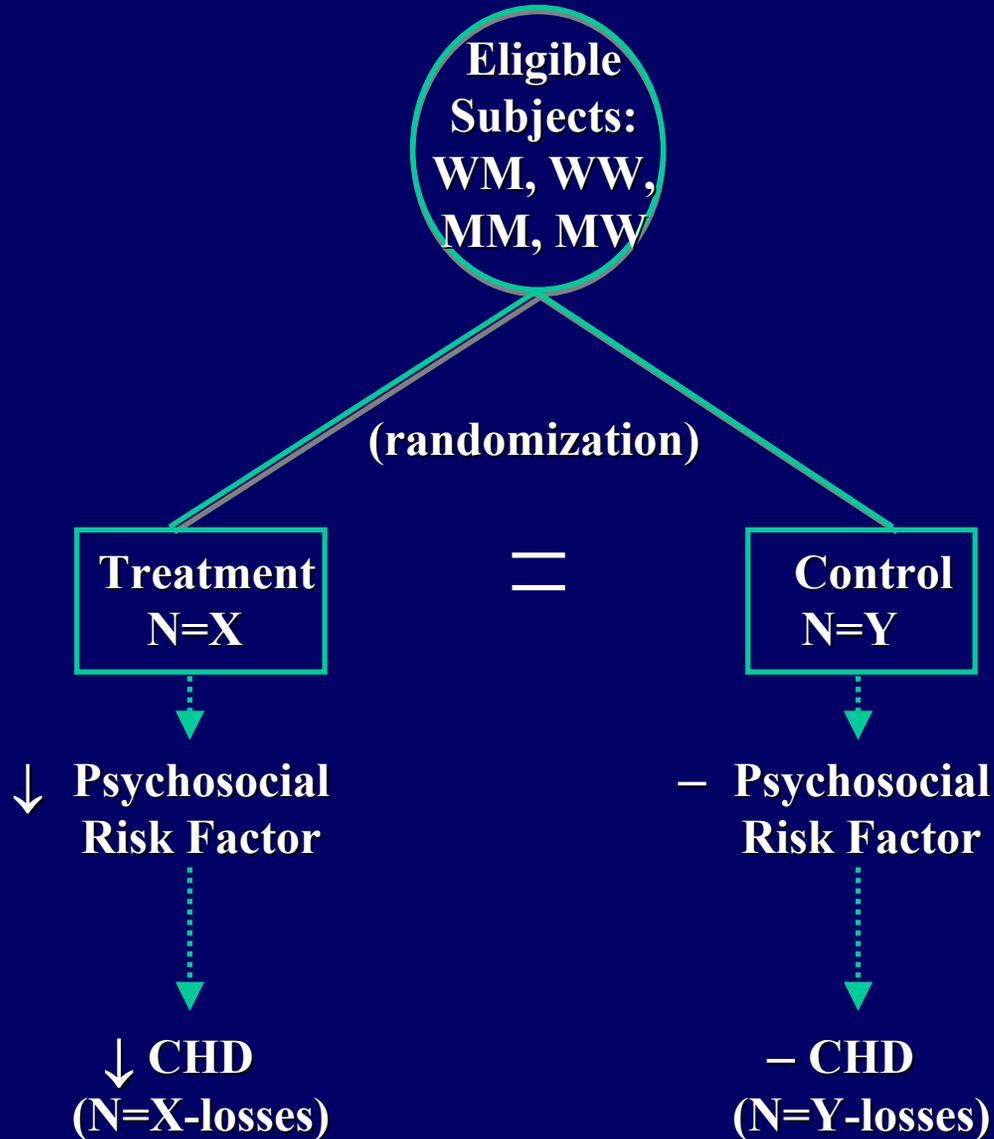


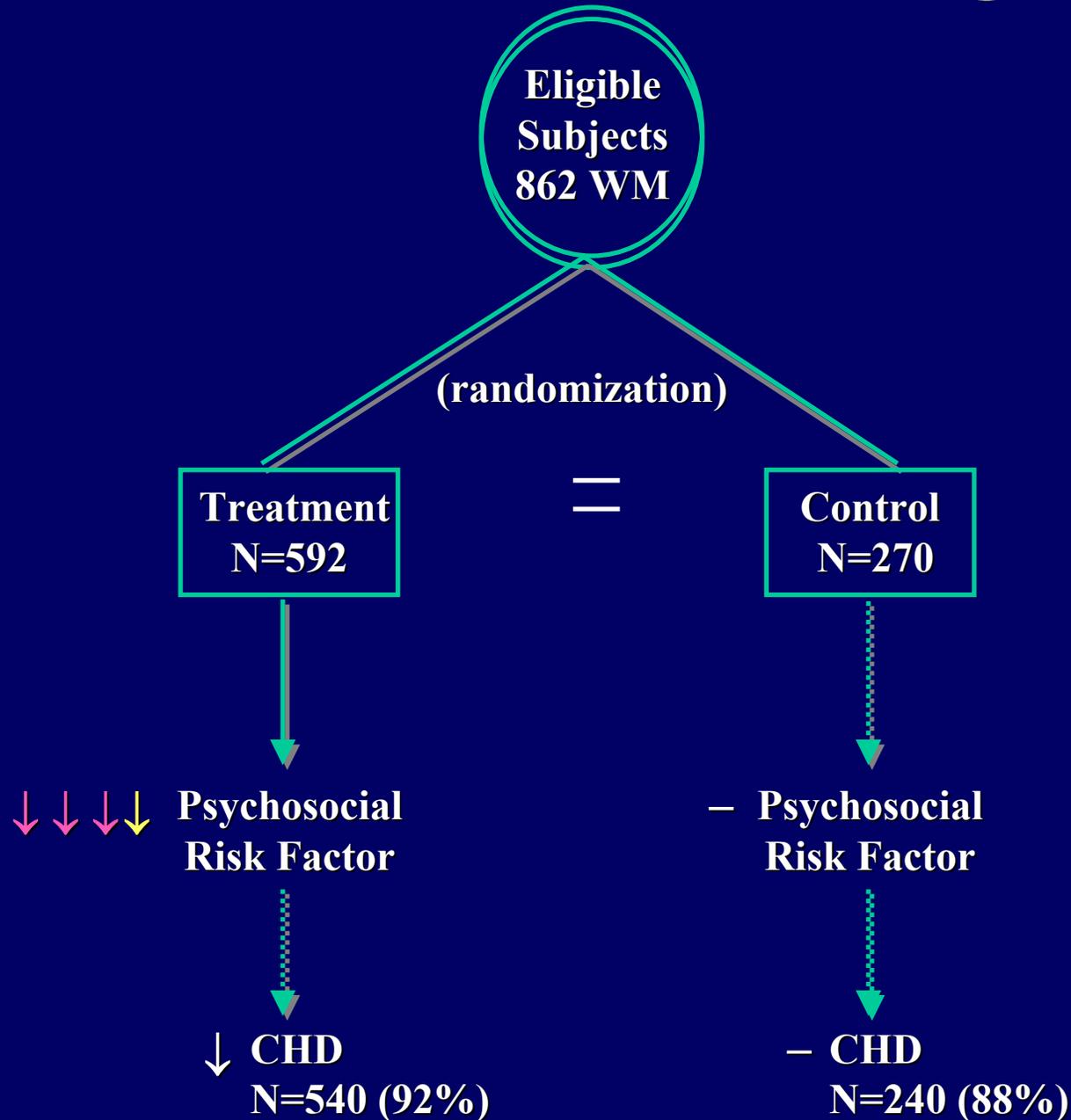
**A Selected History of Behavioral Clinical Trials:  
What Went Wrong?**

Lynda H. Powell, PhD

# Clinical Trial Design



# RCPP Clinical Trial Design



# Impact of RCPP Intervention on Psychosocial Risk Factors

---

	Improved at End of Treatment	Improvement Predicted Subsequent CHD Events
Type A Behavior	***	ns
Hostility	***	ns
Anger	***	ns
Impatience	***	ns
Life Satisfaction	***	ns
Self-Efficacy at Managing Stress	***	*
Social Support	***	ns
Depression	***	**

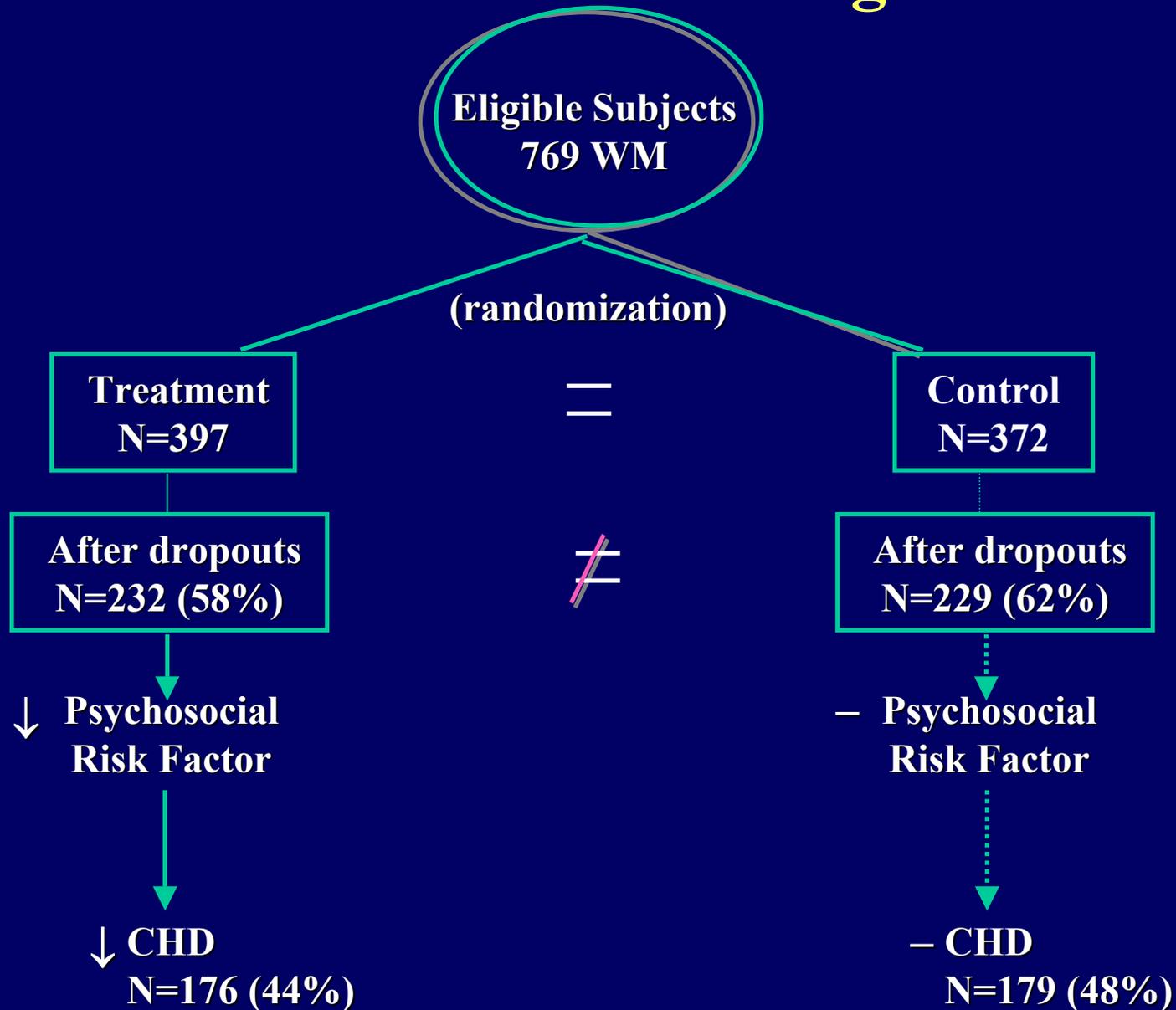
---

\*\*\*  $p < 0.001$

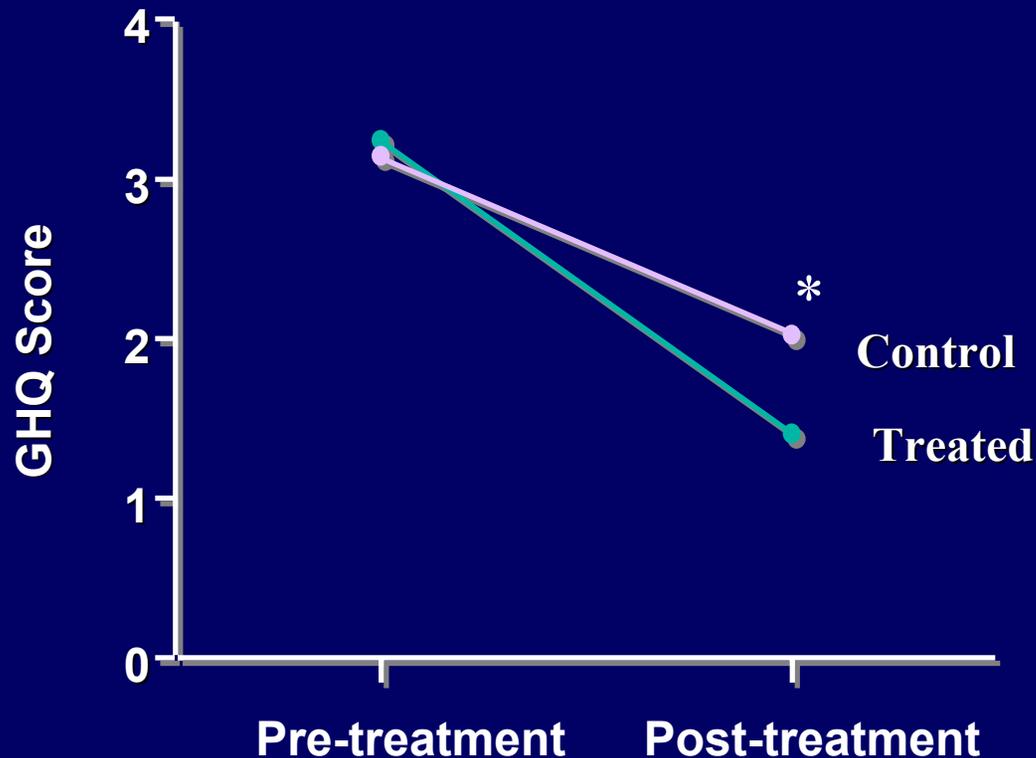
\*\*  $p < 0.01$

\*  $p < 0.05$

# IHD Stress Monitoring Clinical Trial Design



# Reduction in Distress at 1-Year Follow-up



\*  $p < 0.05$

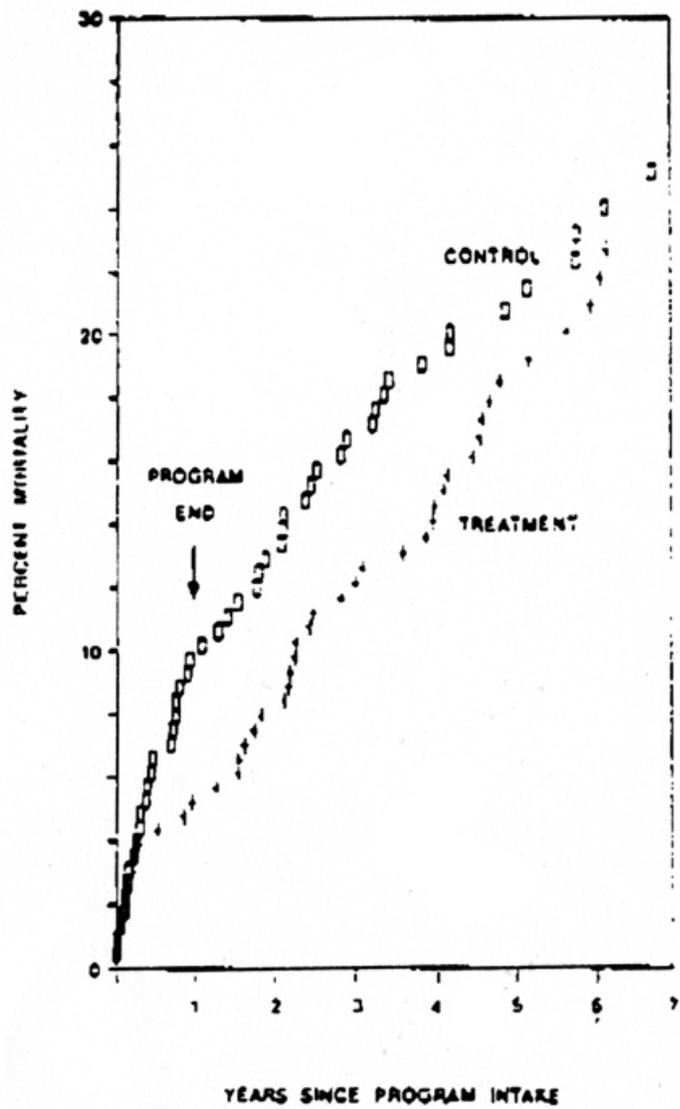


Fig. 1. Cumulative cardiac mortality in the treatment and control groups.

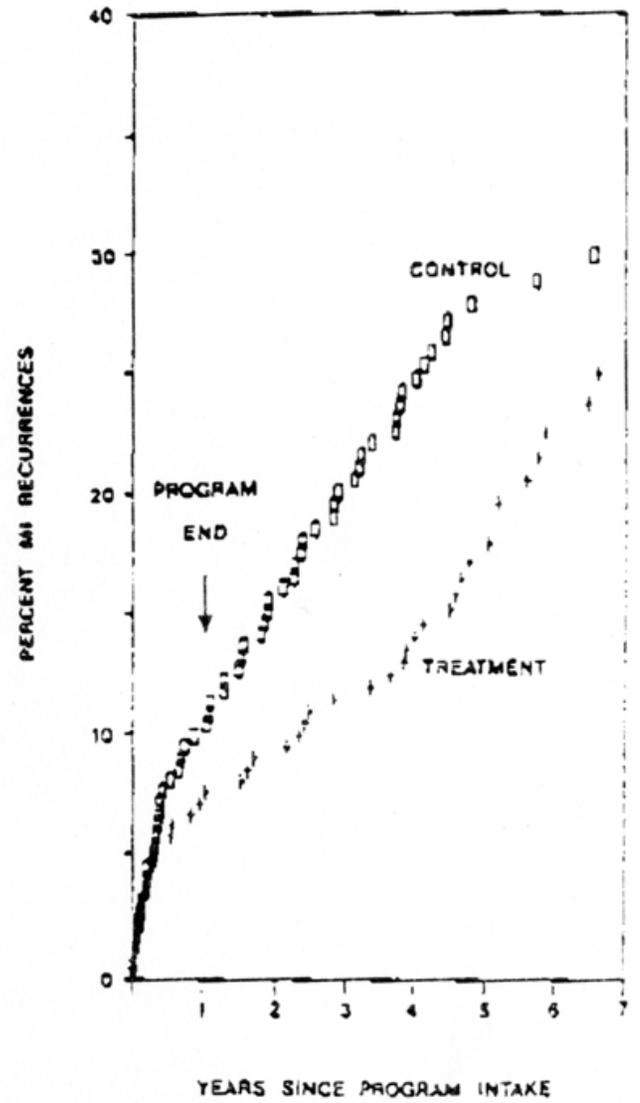
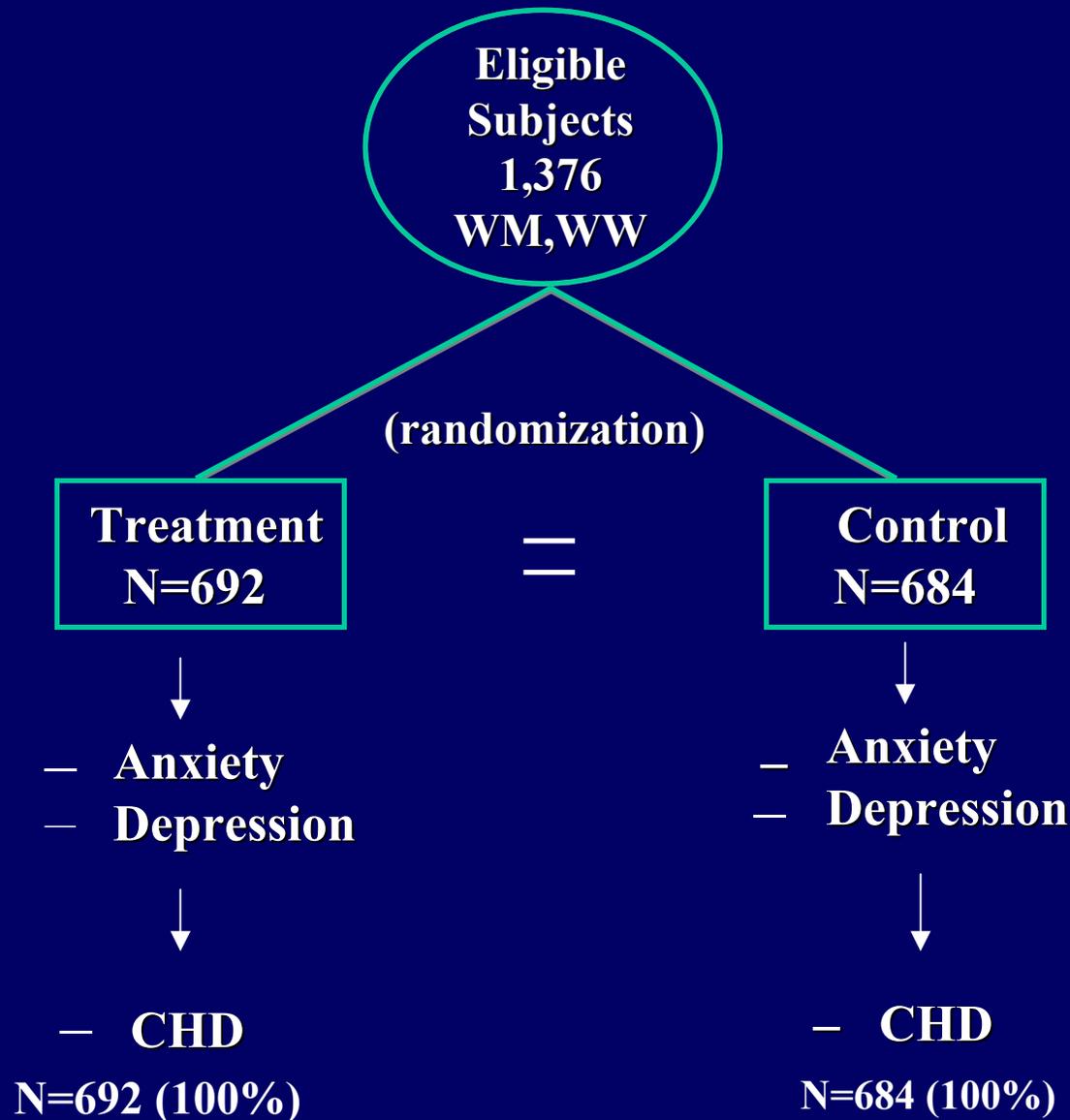


Fig. 3. Cumulative MI recurrences in the treatment and control groups.

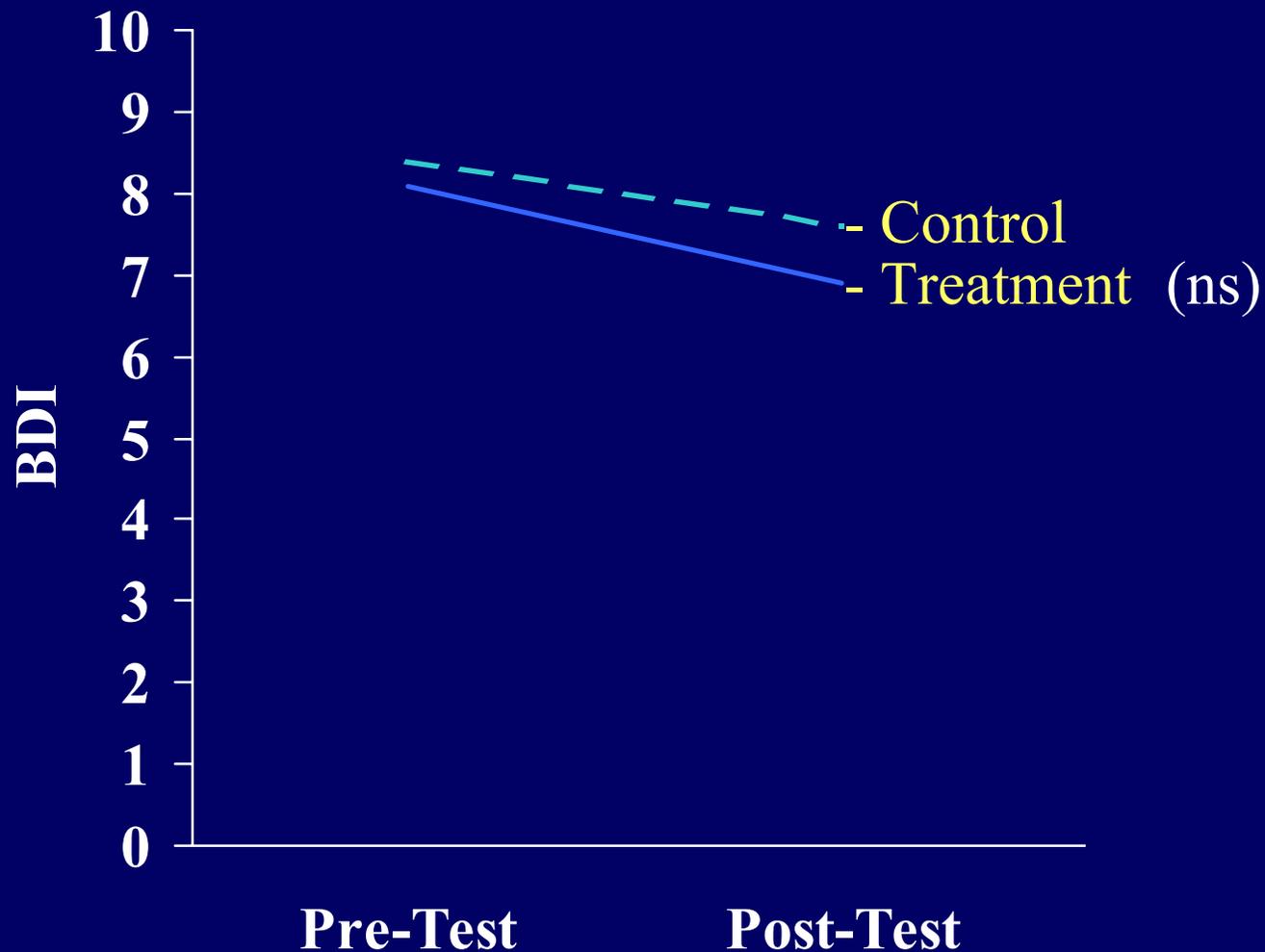
# IHD Stress Monitoring Trial: Baseline Comparability

	Treatment	Control
Education	↓	↑
Occupation: Blue Collar	↓	↑
Income	↓	↑
Need for diamorphine for cardiac pain relief	↓	↑

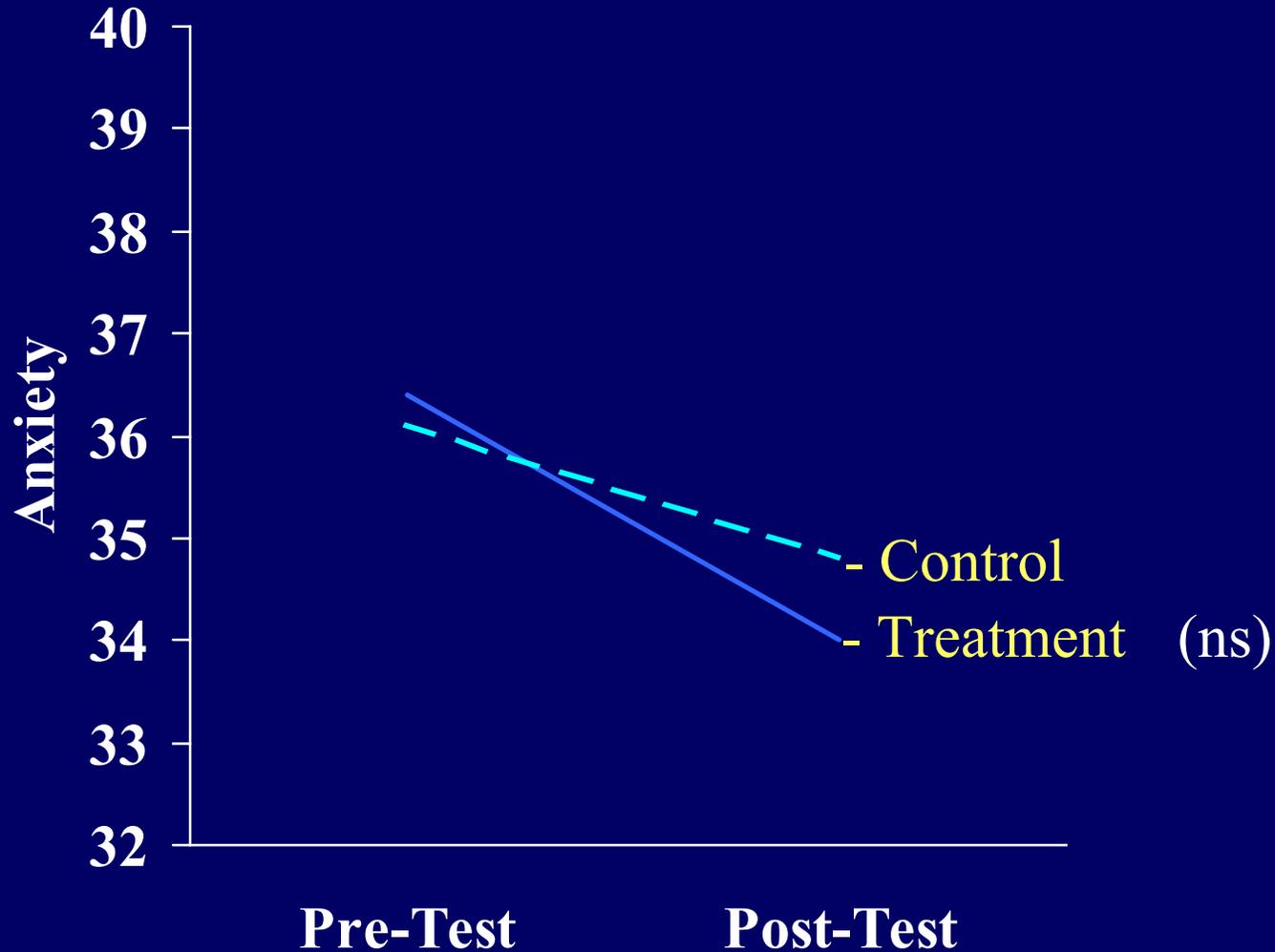
# M-HART Clinical Trial Design

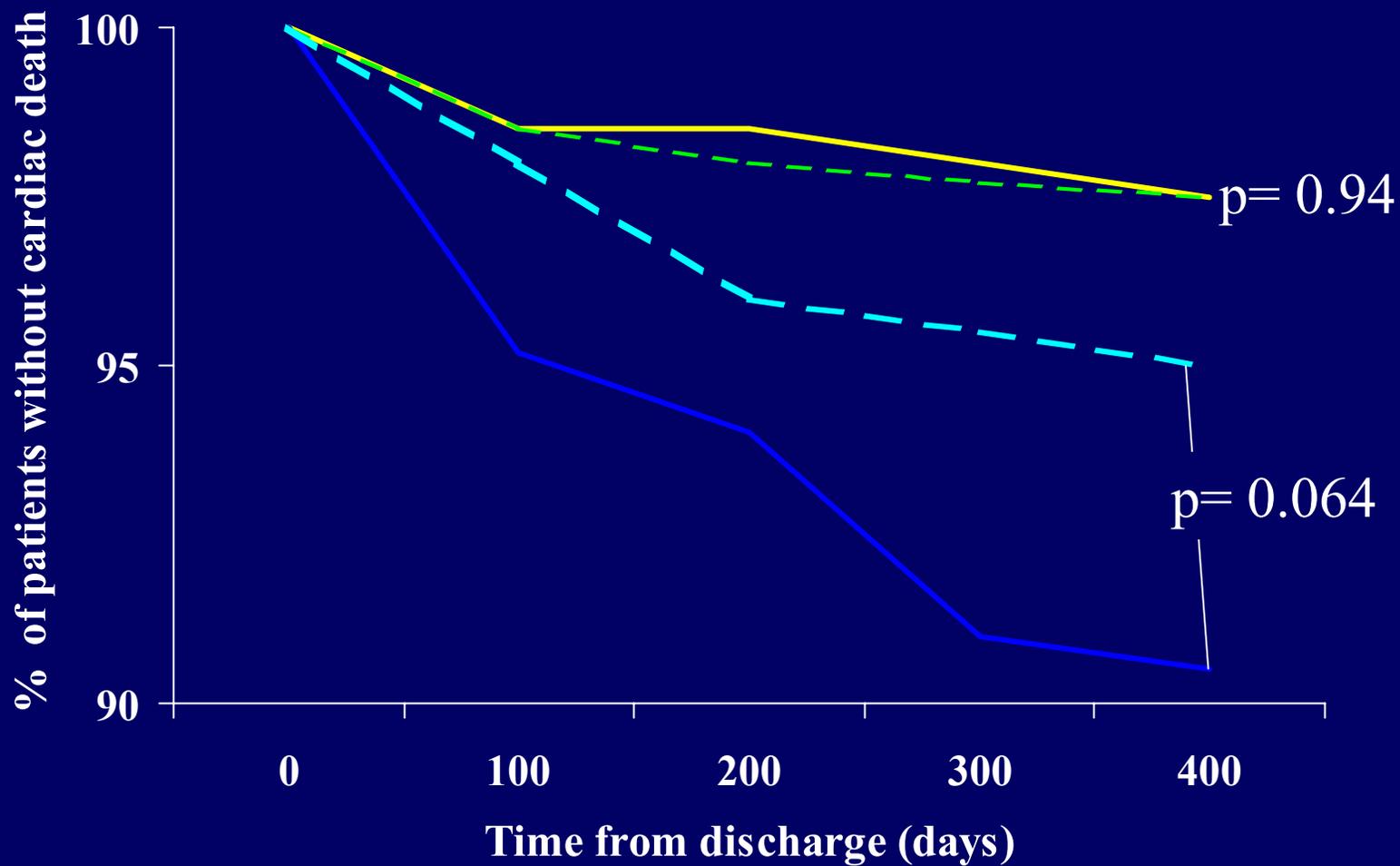


# M-HART Change in Depression



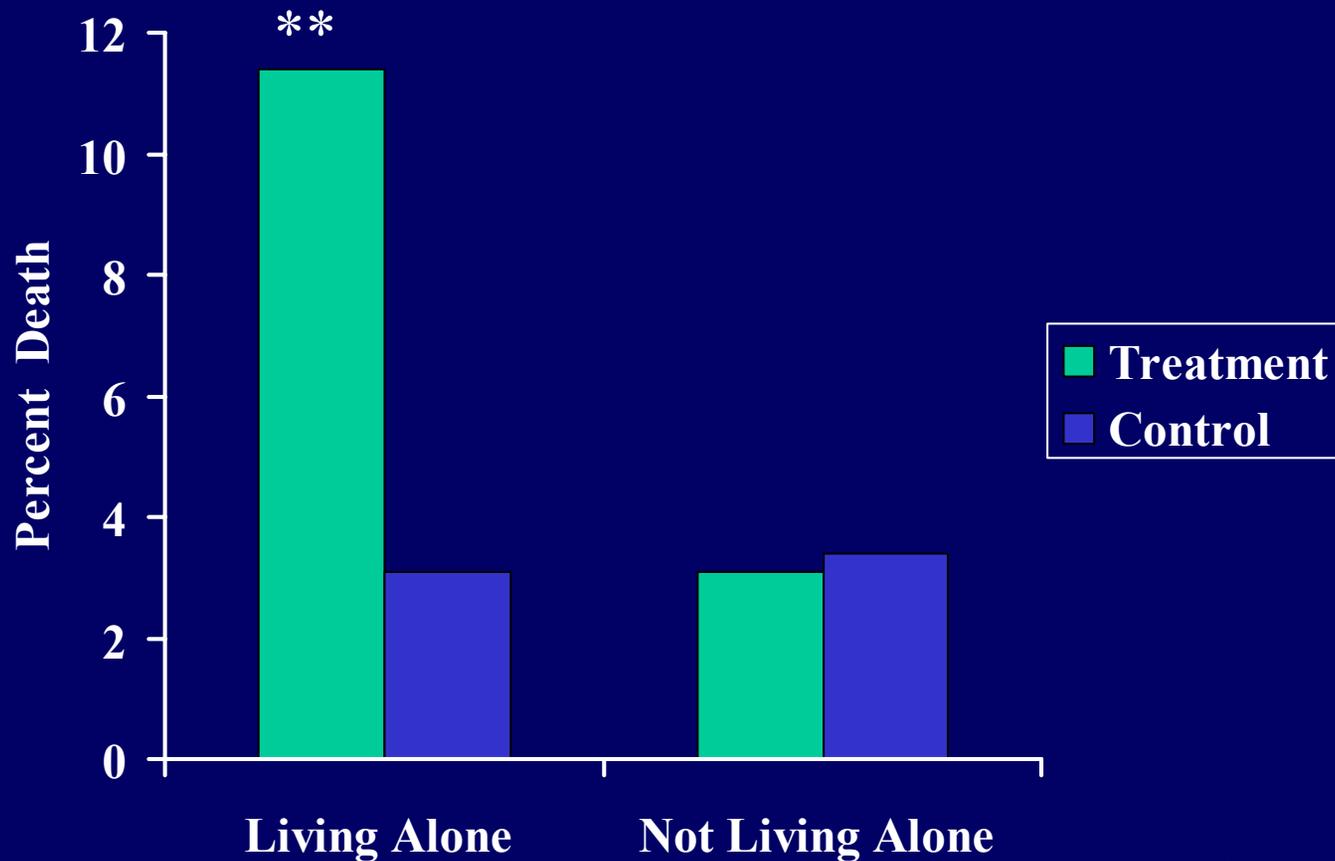
# M-HART- Change in Anxiety





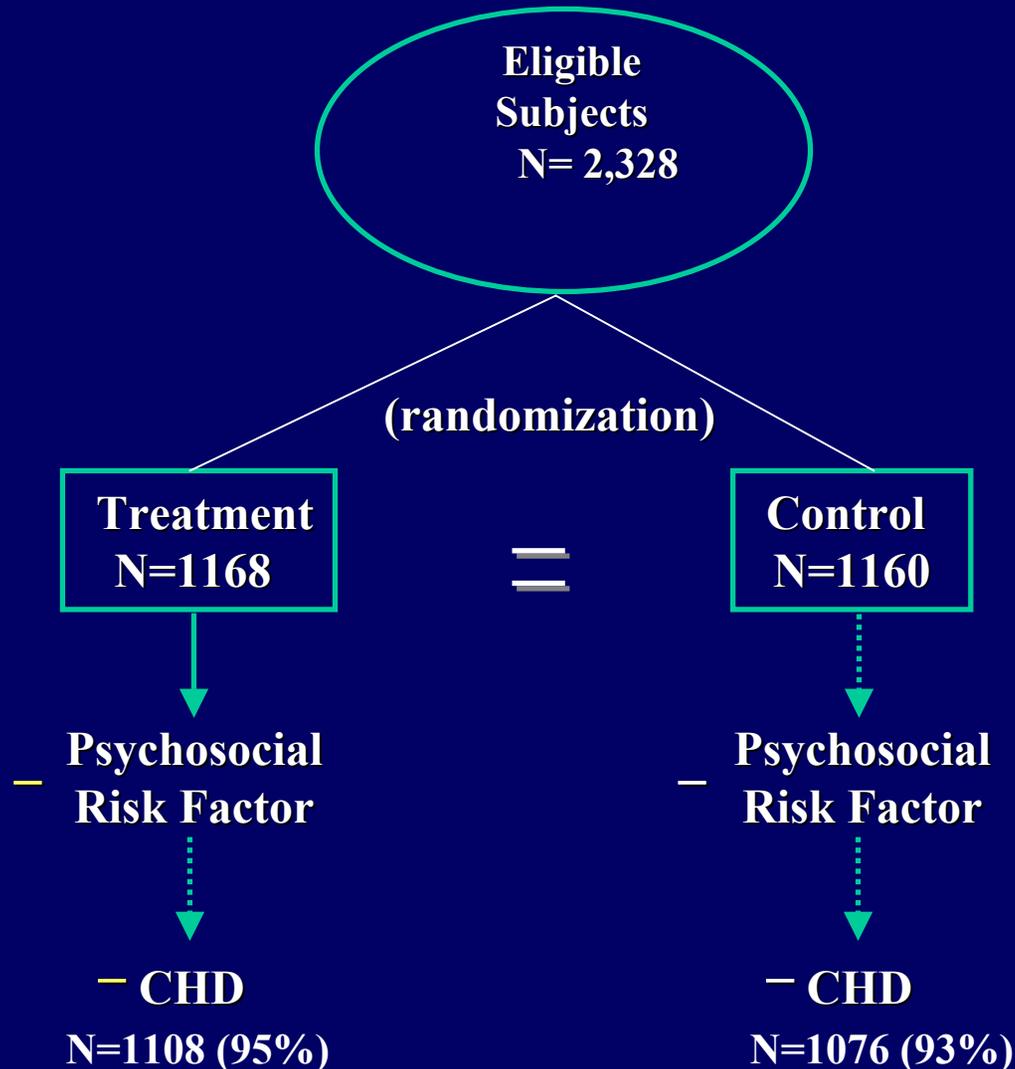
— Intervention men (n=458)      - - - Control men (n=445)  
— Intervention women (n=234)      - - - Control women (n=239)

# M-HART Death By Treatment in Living Alone and Not Living Alone

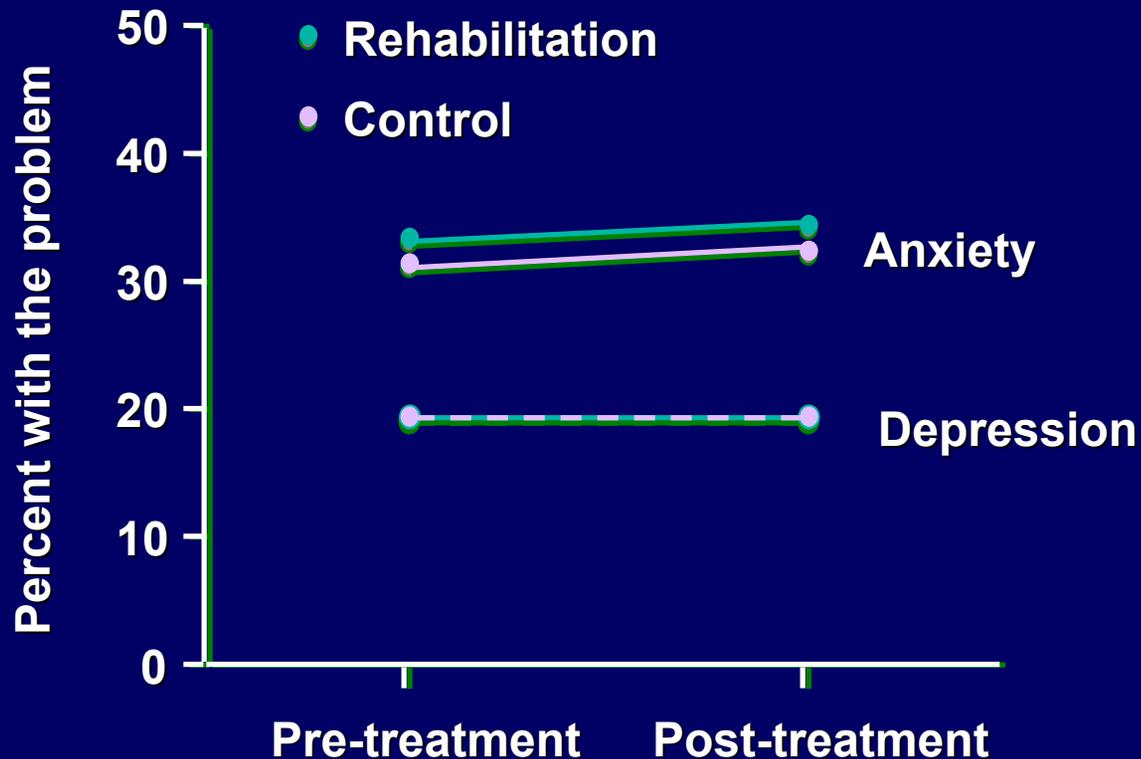


\*\*p=0.01

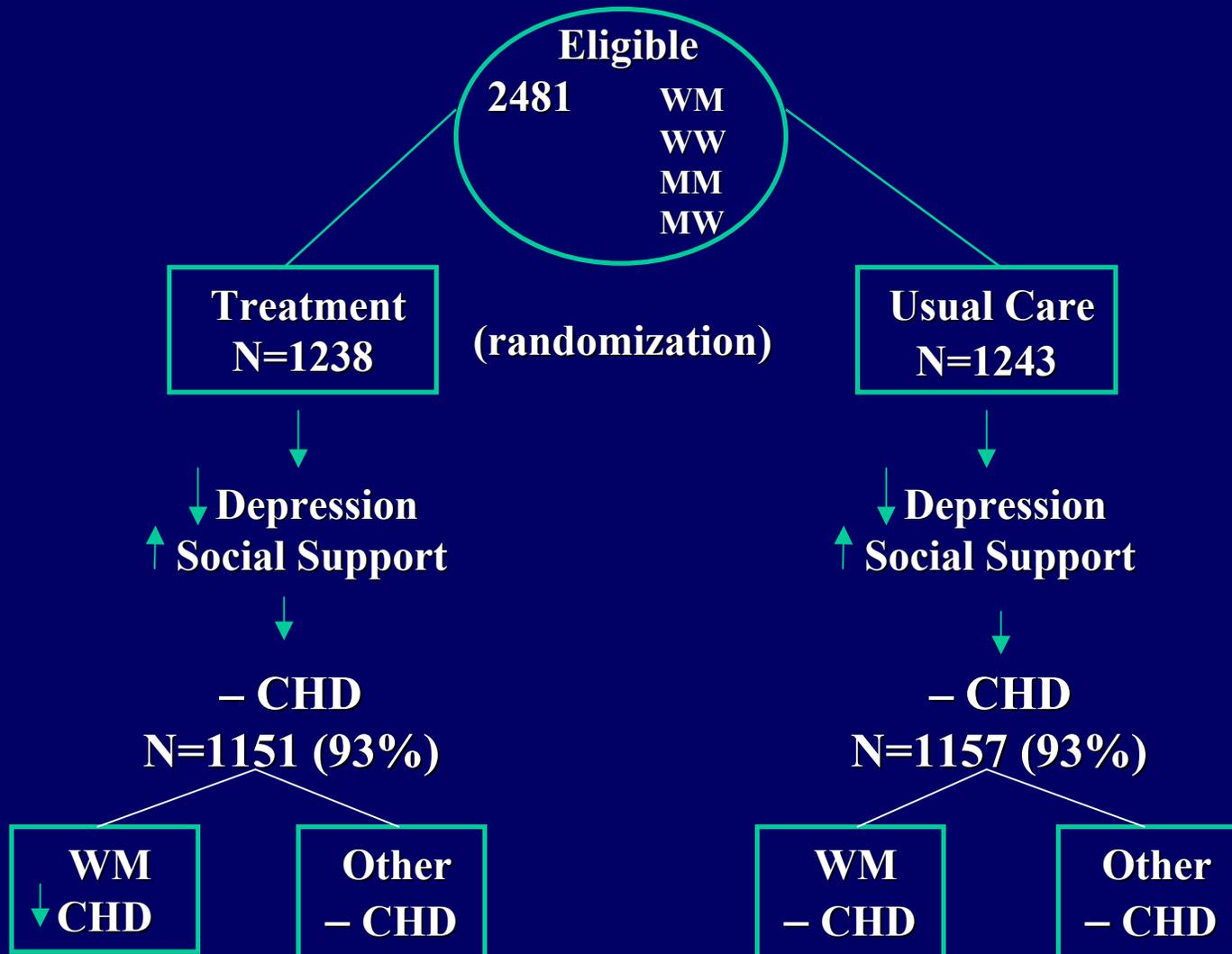
# Jones & West Rehabilitation Program Clinical Trial Design



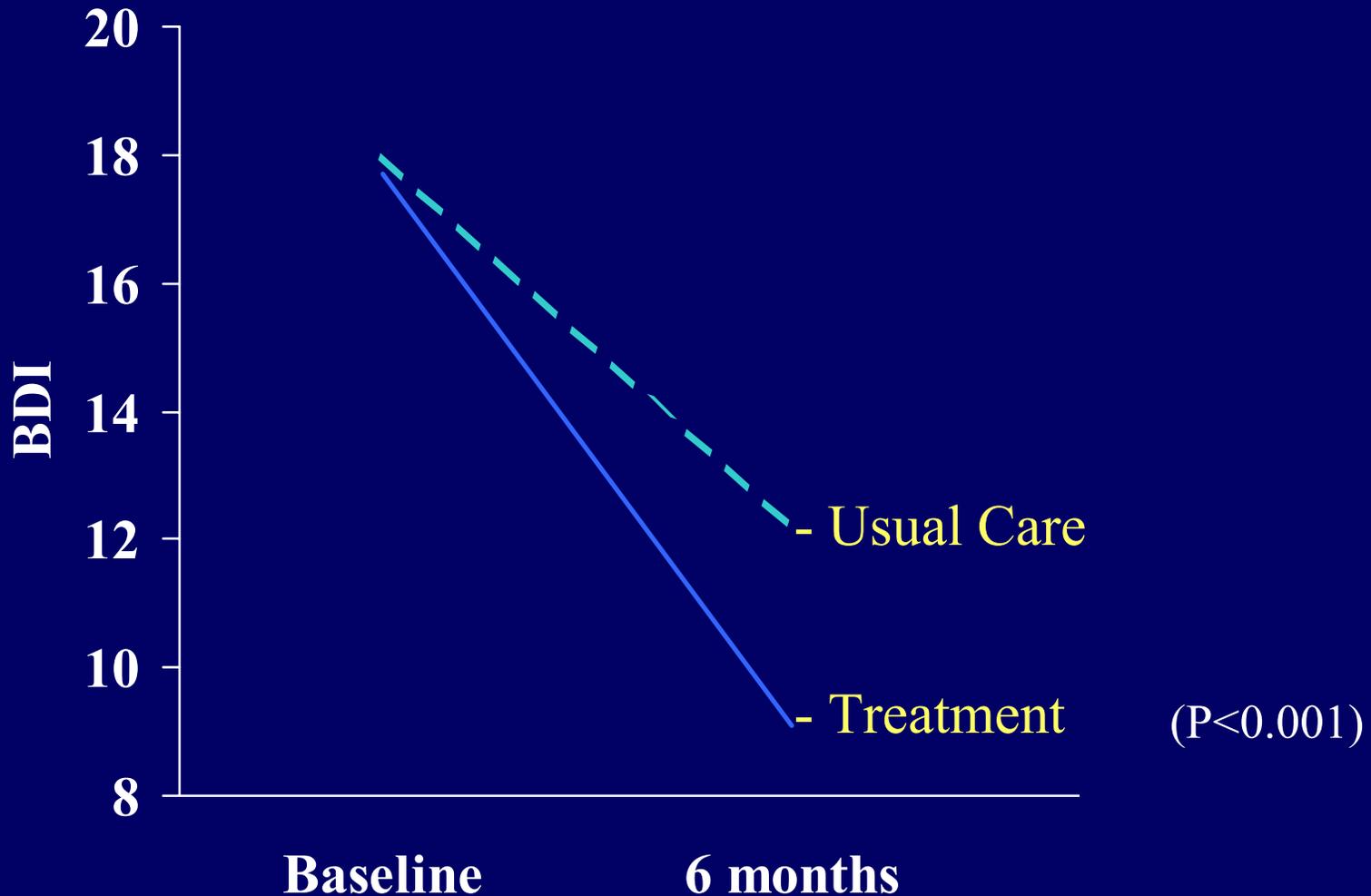
# Reduction in Anxiety and Depression at 6-Month Follow-up



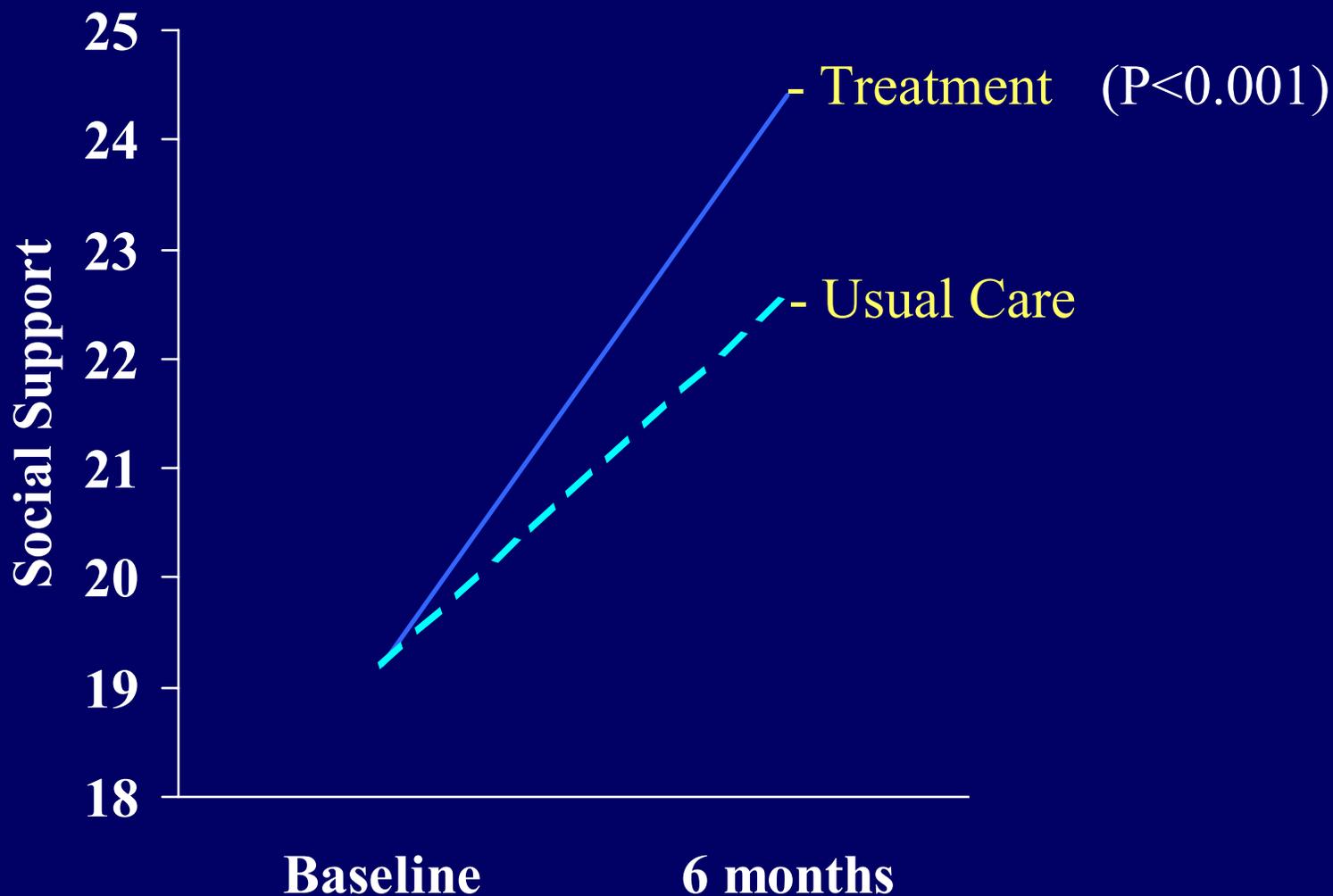
# ENRICHD



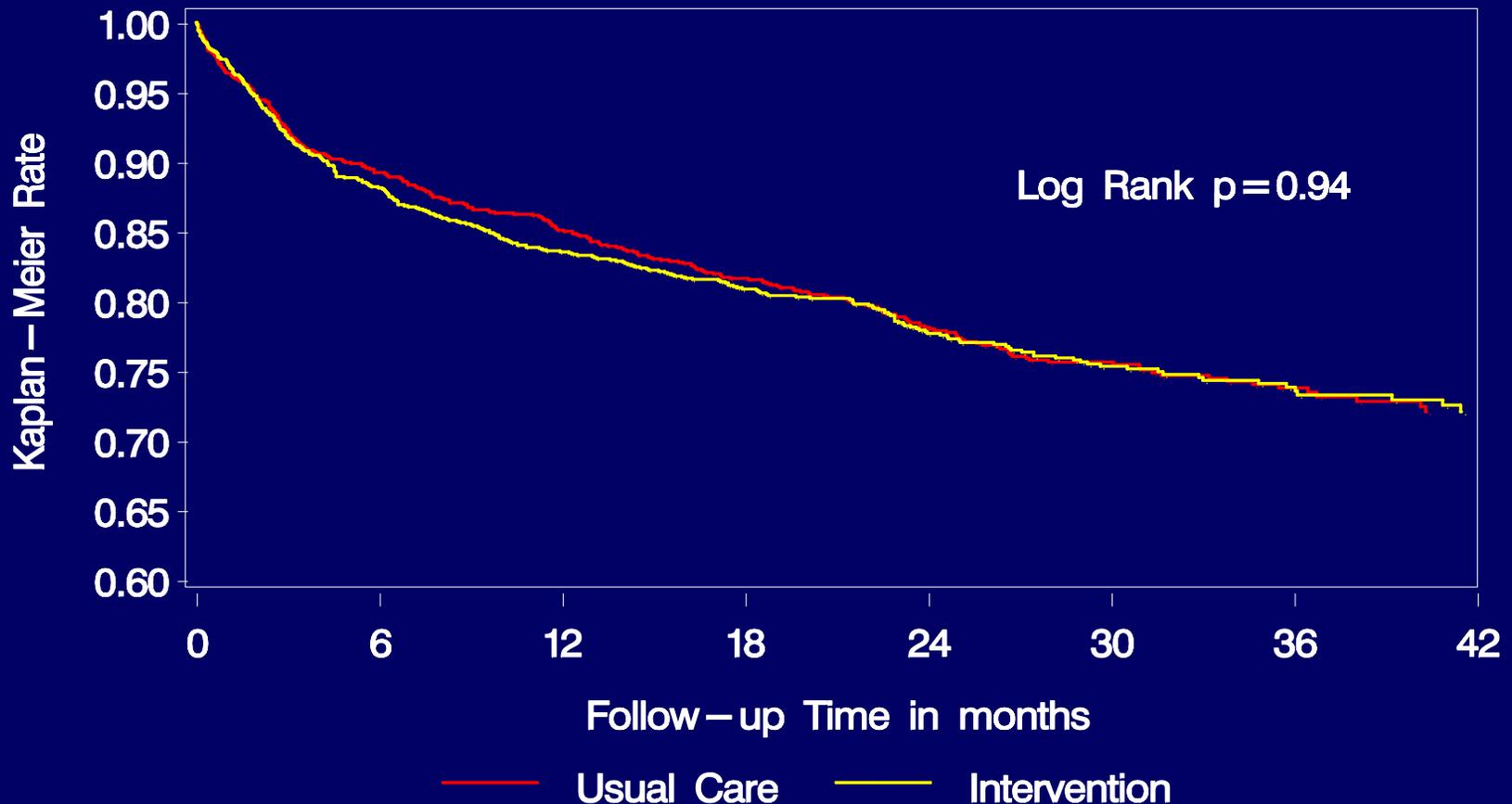
# ENRICHD: Change in Depression



# ENRICHD: Change in Social Support



# Kaplan-Meier Survival Curves



# ENRICHD: Primary Endpoint



# Summary

---

1. A behavioral intervention can harm. Understand the beliefs and attitudes of all targeted subgroups including women, minorities, and people of lower educational levels.
  2. Pilot the intervention first. Be completely confident in its efficacy before undertaking a clinical trial of its impact on health. Be particularly sensitive to gender and minority variation in response.
  3. Randomize and guard the randomization throughout the trial. Randomization provides the best control for the measured and unmeasured confounders available.
  4. Be objective and humble. Science moves slowly. Remain open to the possibility that the intervention:
    - will not work;
    - will be misinterpreted;
    - will not be accepted in the larger community if it does work.
-