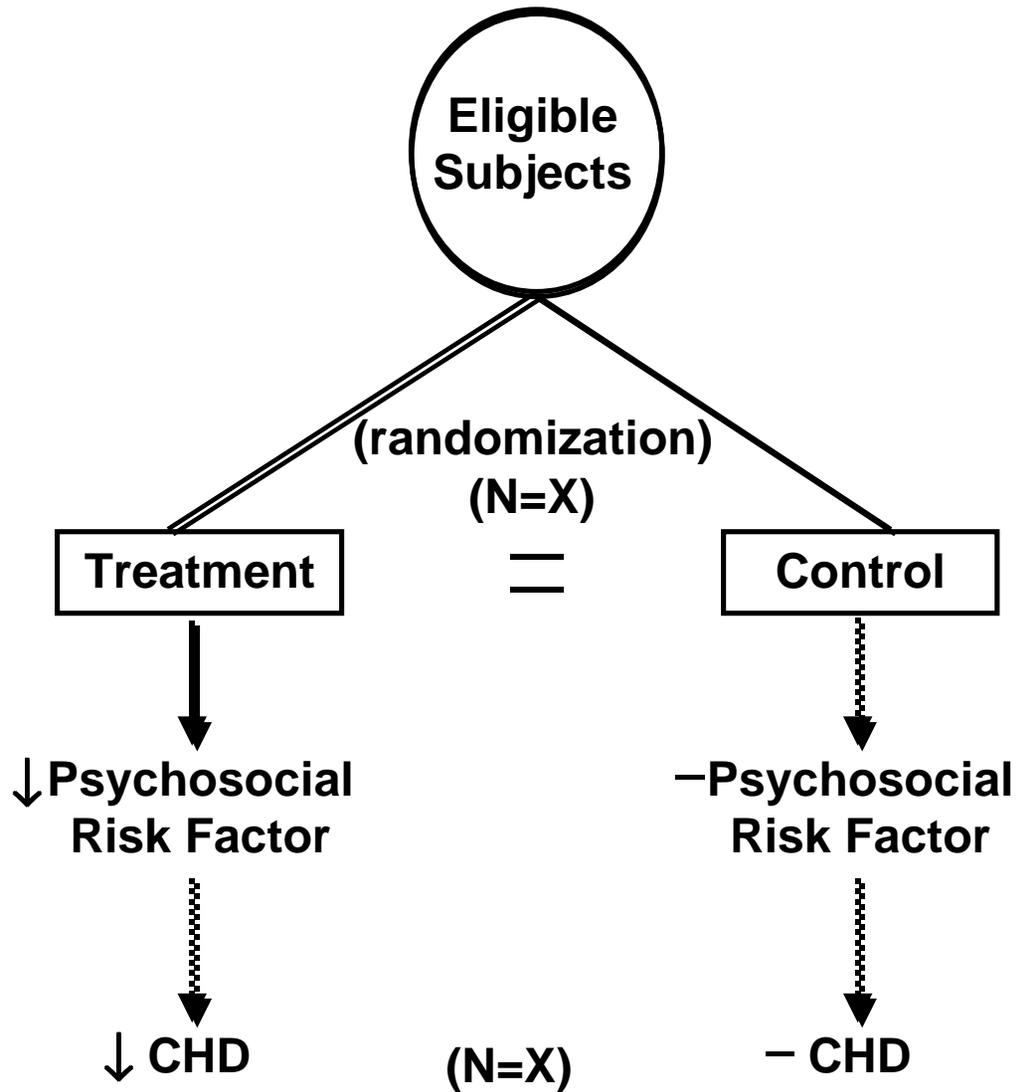


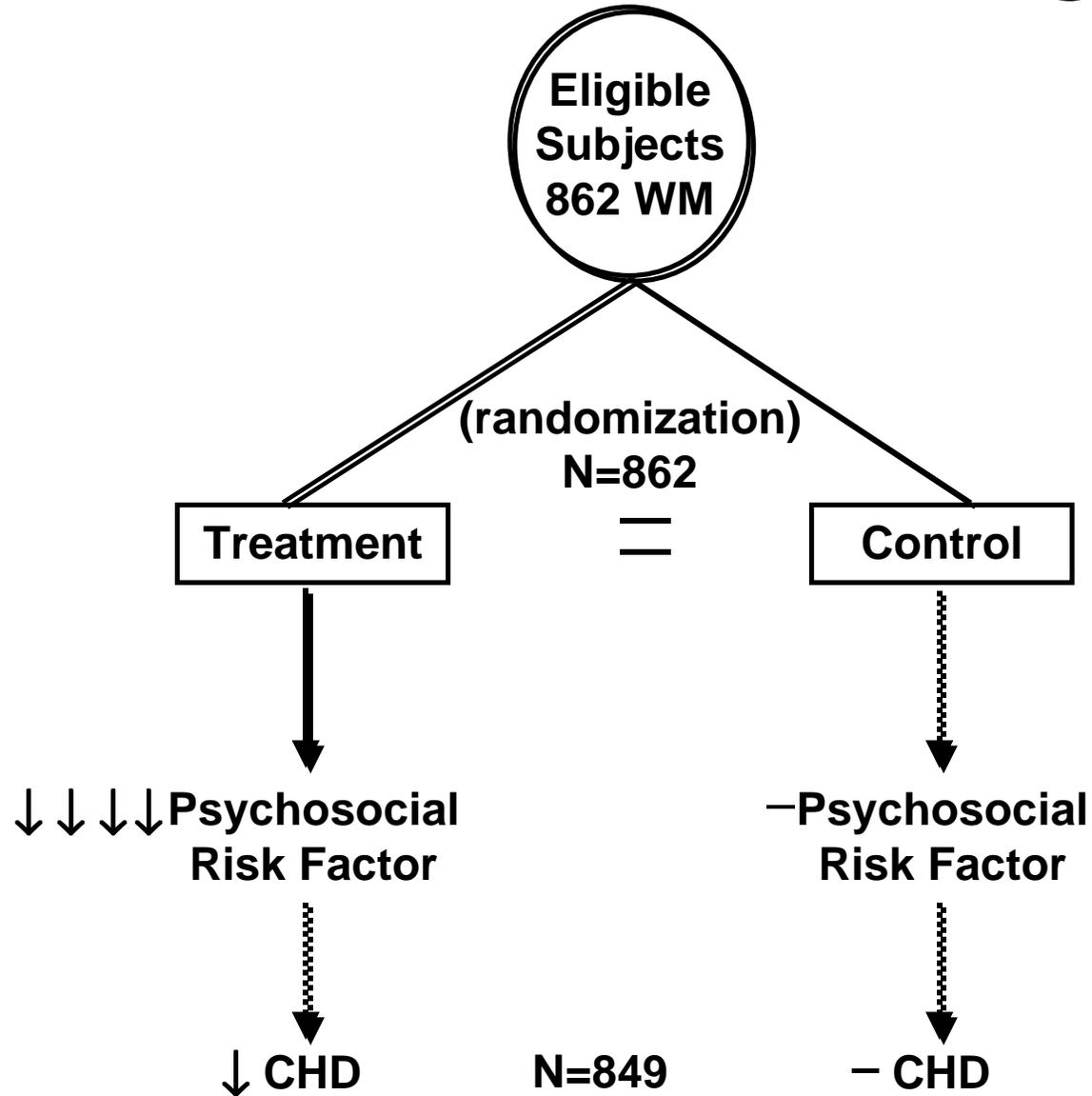
A Selected History of Behavioral Clinical Trials:
What Went Wrong?

Lynda H. Powell, PhD

Clinical Trial Design



RCPP Clinical Trial Design



Impact of RCPP Intervention on Psychosocial Risk Factors

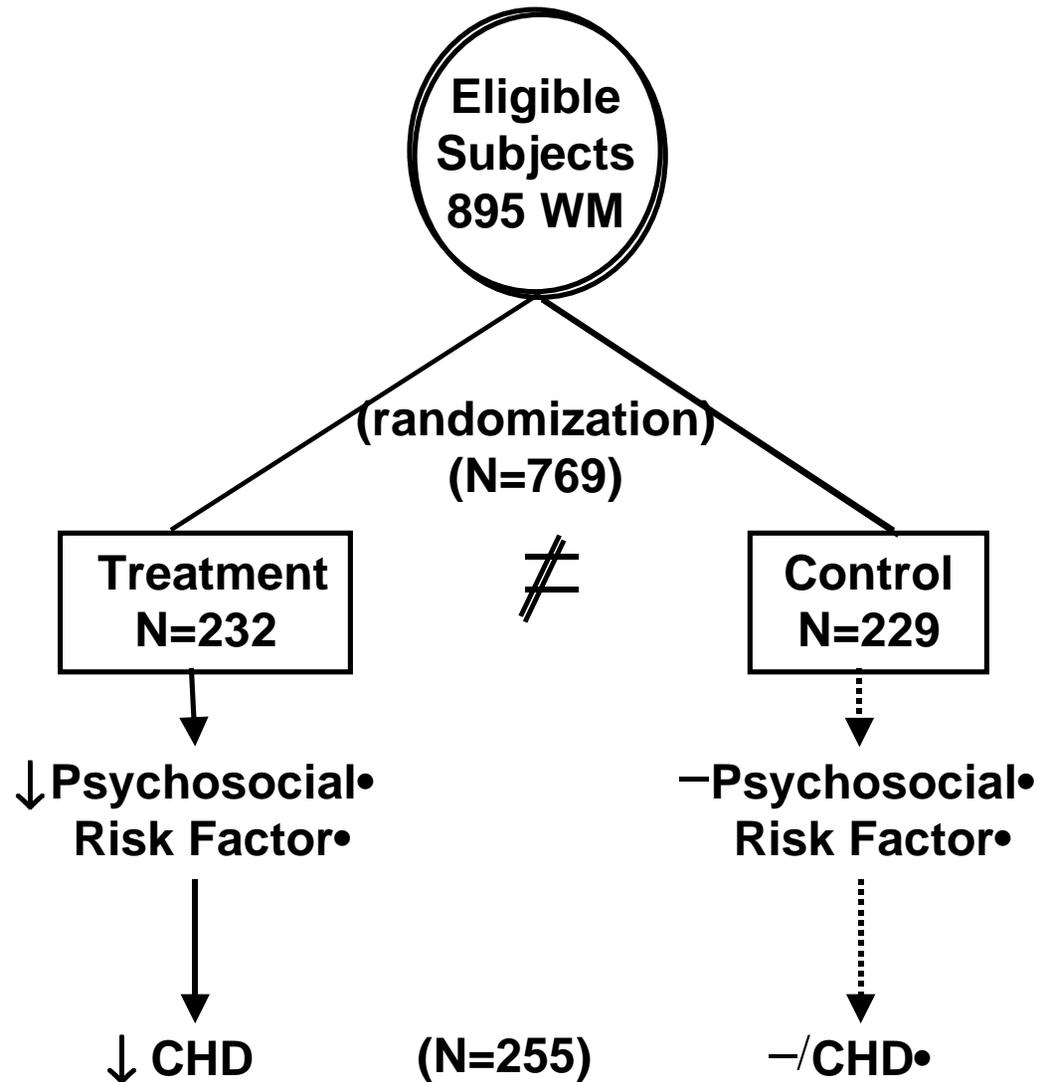
<u>Improved at End of Treatment</u>	<u>Improvement Predicted Subsequent CHD Events</u>
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***** p < 0.001**

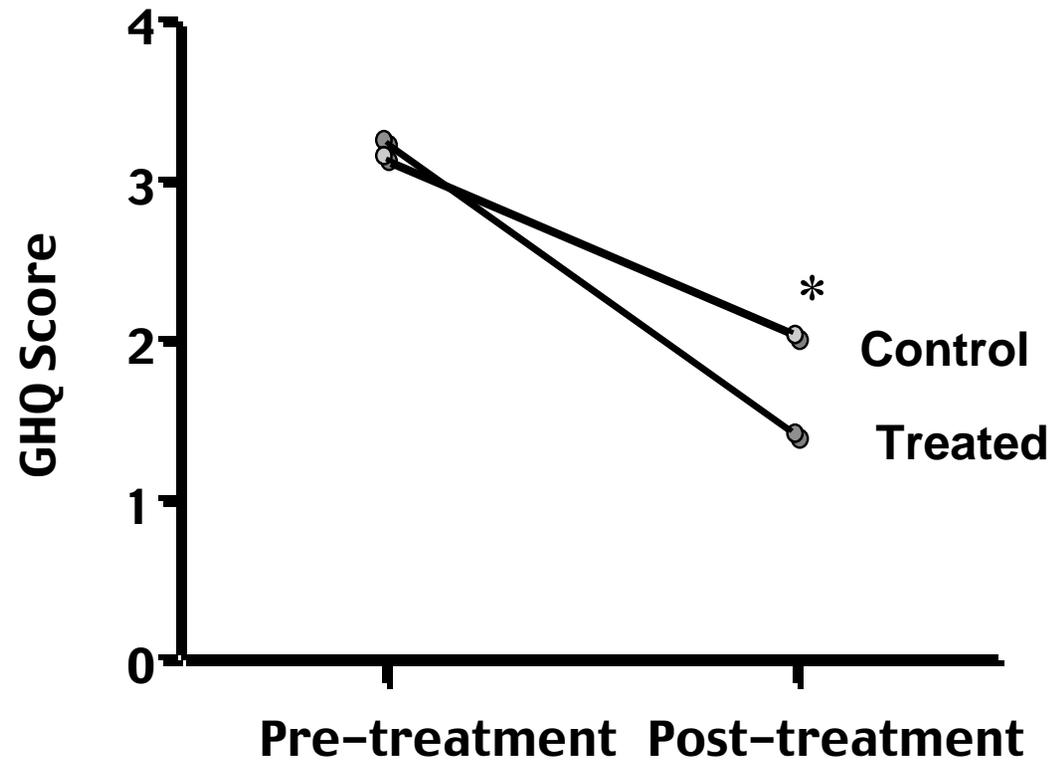
**** p < 0.01**

*** p < 0.05**

IHD Stress Monitoring Clinical Trial Design



Reduction in Distress at 1-Year Followup

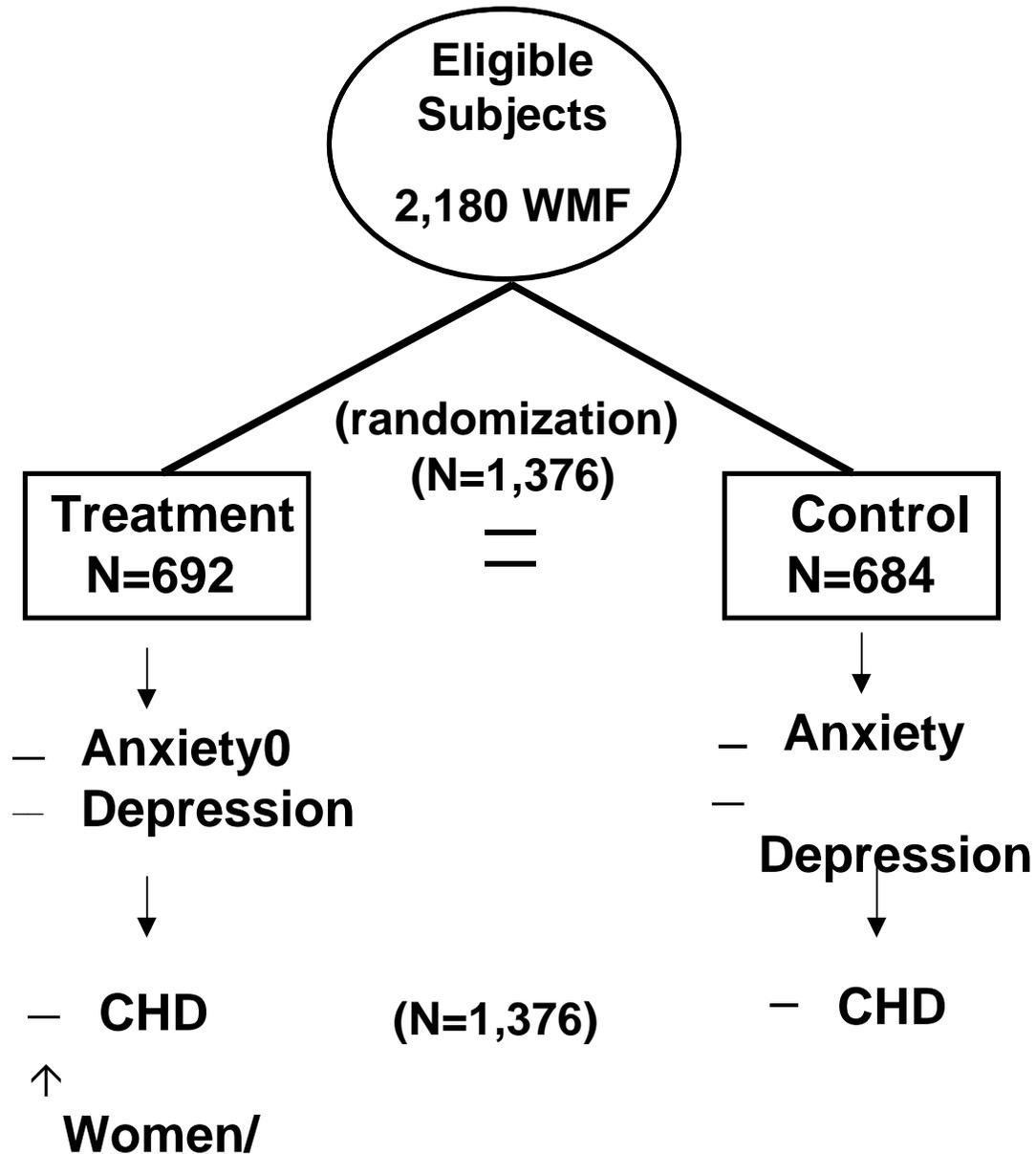


* $p < 0.05$

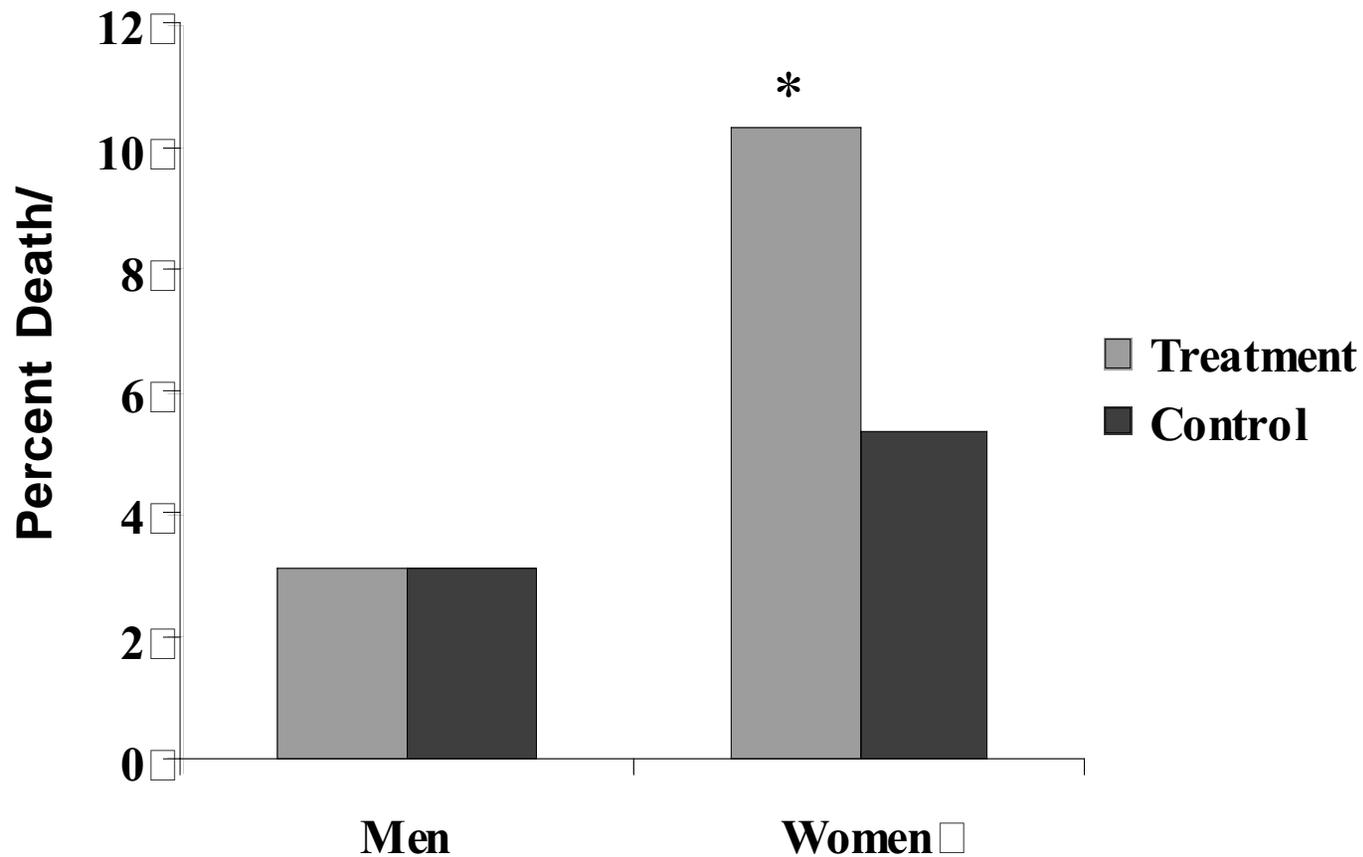
Frasure-Smith & Prince,
1985

IHD Stress Monitoring Trial: Baseline Comparability

M-HART Clinical Trial Design



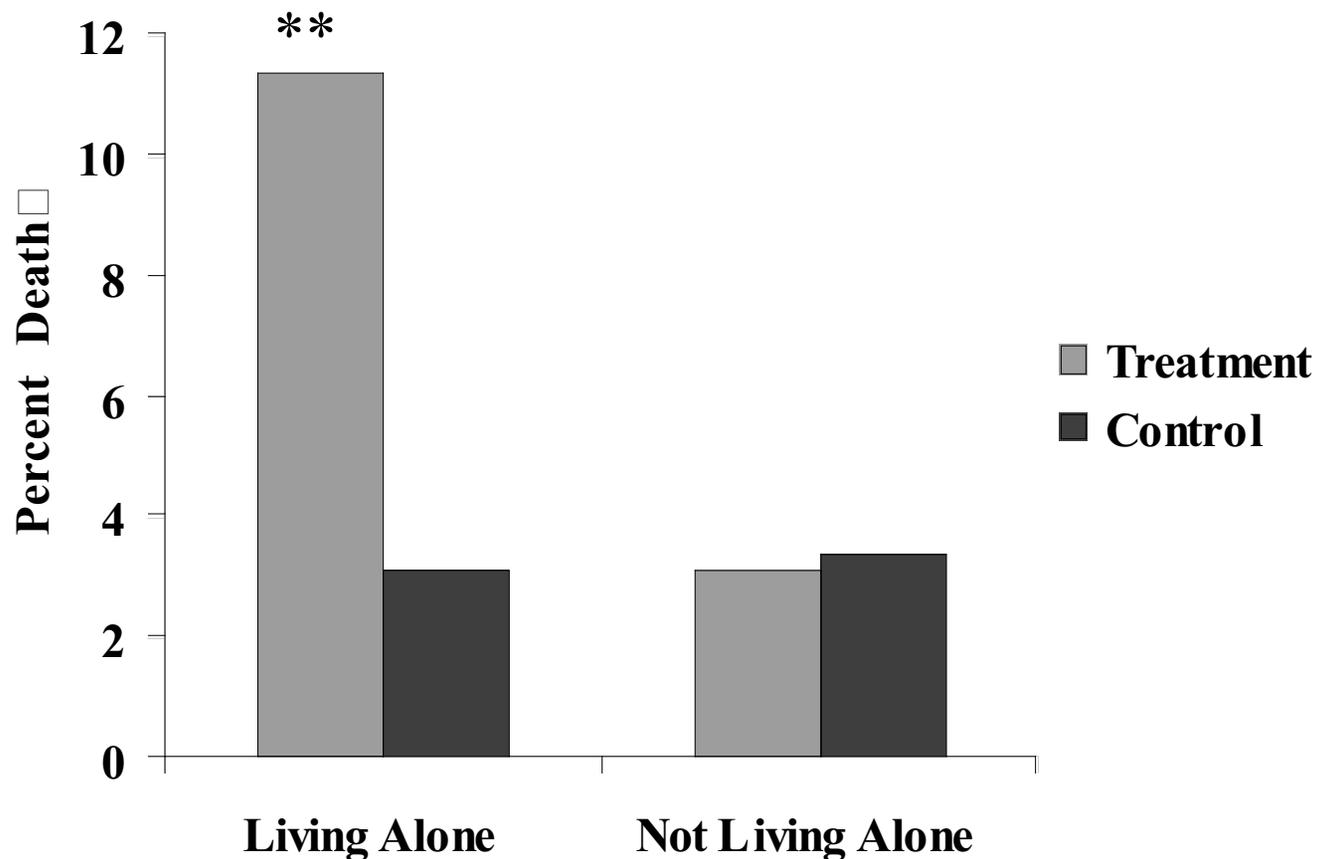
M-HART Death By Treatment in Men and Women



Frasure-Smith et al, Lancet, 1997

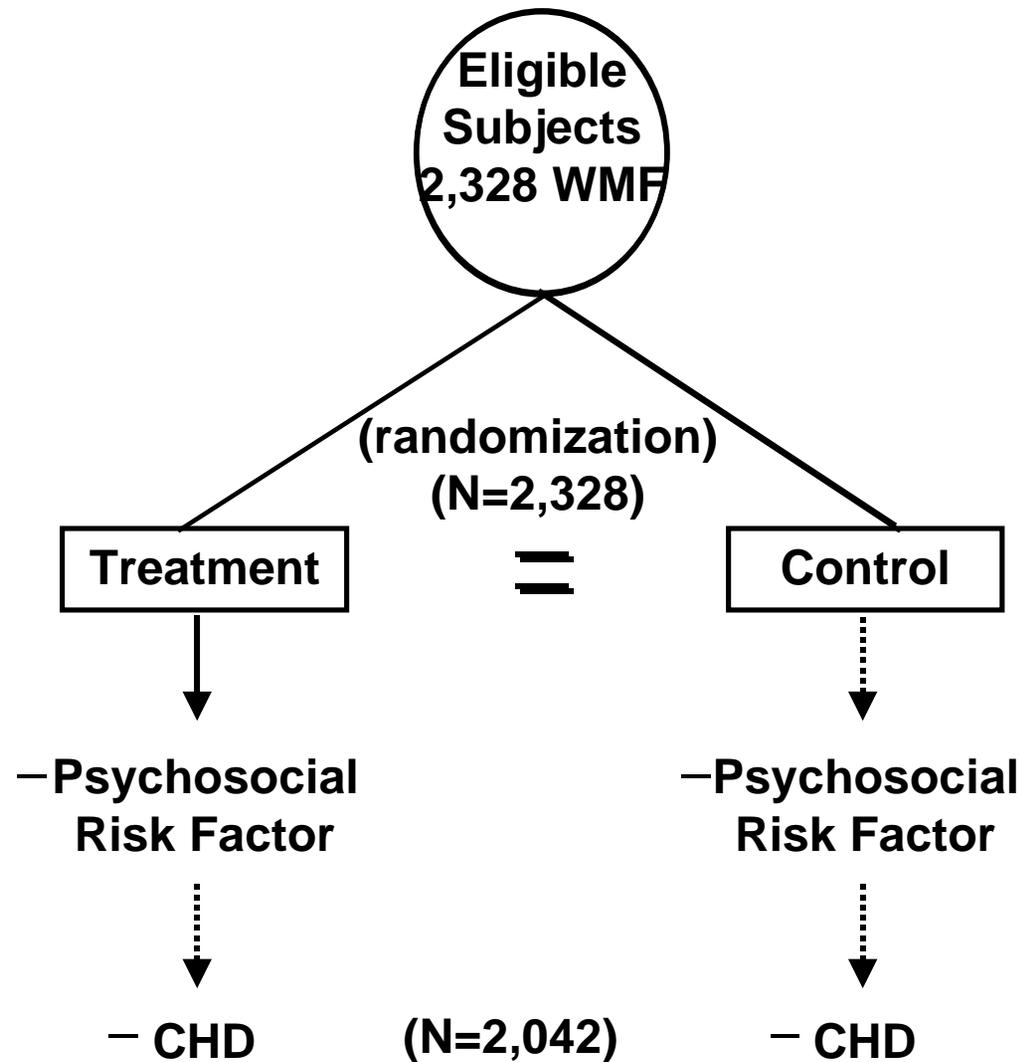
*p=0.05

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

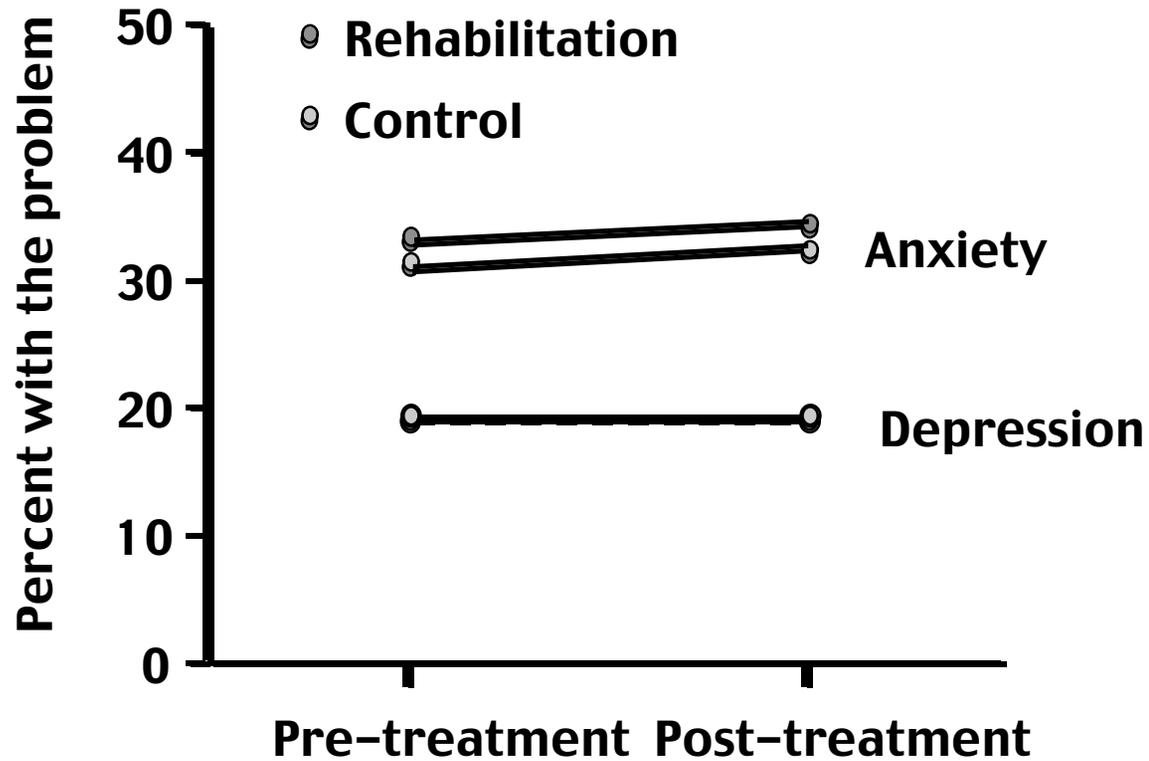


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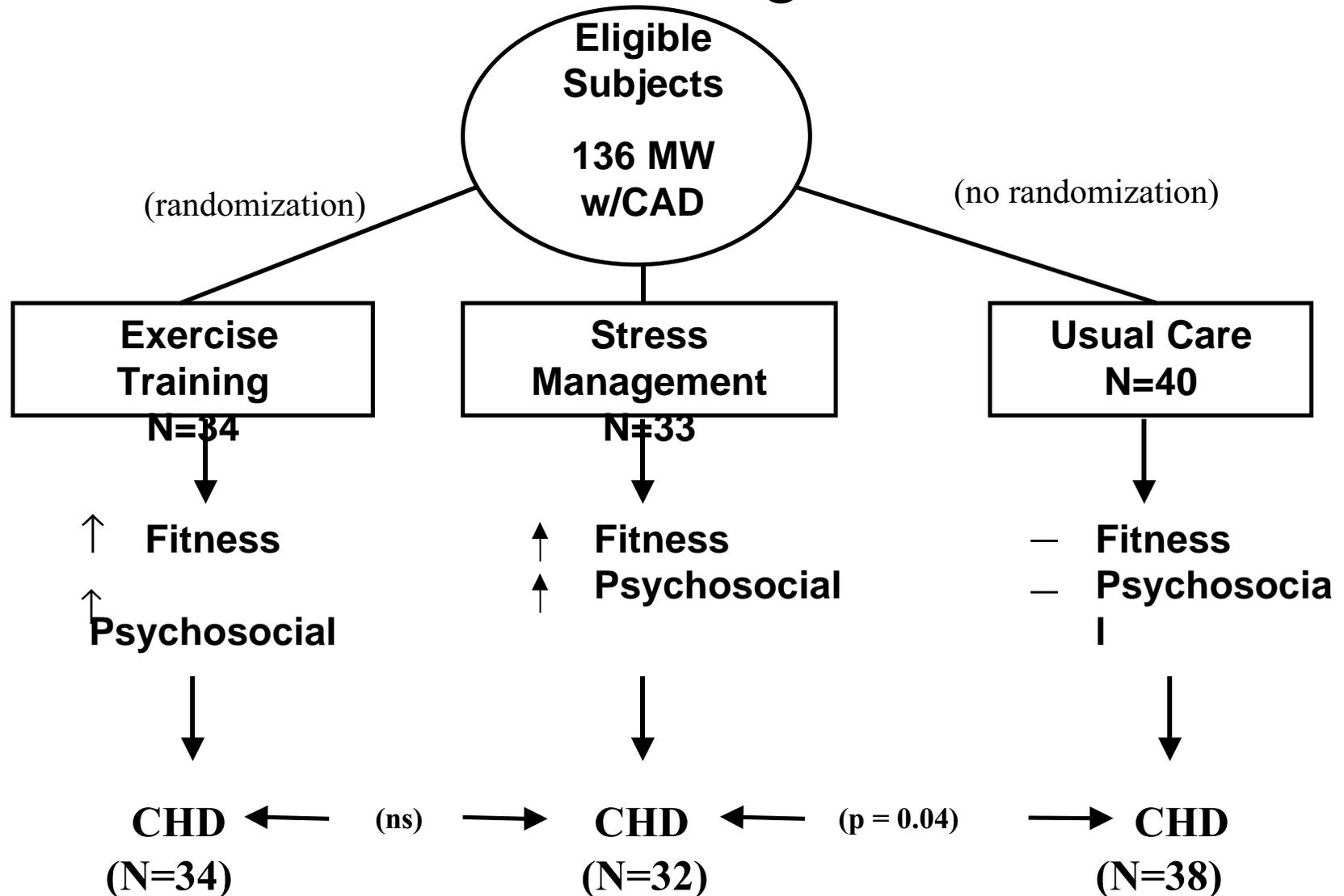
Jones & West Rehabilitation Program Clinical Trial Design



Reduction in Anxiety and Depression at 6-Month Followup



Myocardial Ischemia Intervention Trial Design



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.
 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.
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