

Retention Issues & Strategies in Longitudinal Studies

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Objectives

- To Provide an Overview and Discussion Regarding
- ◆ Why Retention of Research Participants is Important
- ◆ The Impact of Lost to Follow-Up or Poor Adherence
- ◆ Strategies to Retain Participants in Studies

Retention of Subjects

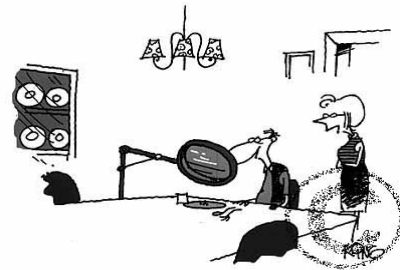
- ◆ Range of Drop Outs: 0 to > 50%
- ◆ Definition of Drop Out
 - Failure to Complete
 - Off of Intervention
 - Withdrawn by Investigator
 - Refusal to Continue

Why Should We Retain Participants?
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POWER

The Ability to Detect an Effect If It Exists



"The magnifying glass makes it look
as if you're still eating the same
amount before going on your diet."

Power is Affected By:

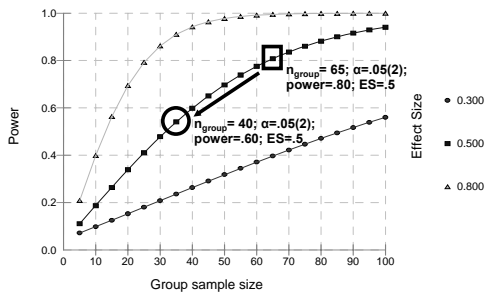
- ◆ The Size of the Sample
- ◆ The Magnitude of the Effect
(difference between groups)
- ◆ The Duration of Observation
- ◆ Adequacy or Completeness of Treatment

Adequate Number of Ss

**Who Completes the Trial
Not Who Enters It**



The Effect of Reduced Sample Size



Reasons for Reduction in Sample Size

- ◆ Inadequate Recruitment
- ◆ Drop Outs
- ◆ Poor Adherence

THE FULL COHORT IS IMPORTANT



**Cholesterol By Treatment Group –
Full Cohort**

	Baseline	6 months	Difference
Drug	263 ± 31.8 mg/dl	211 ± 35.6	50 ± 29
Placebo	263 ± 32.0 mg/dl	258 ± 34.5	6 ± 26

Can Dropouts and/or Poor Adherers
Change Study Results?

YES!

**Adherence
and
Interpretation of Clinical Trials ¹**

Significance of Differences Between Means
- Adjusted and Unadjusted For Compliance-

Treatment Variable	Adjusted	p	Unadjusted	p
Active Joints				
Phenylbutazone	2.79	.01	3.49	.20
Placebo	4.02		4.03	
C20410	2.65	.01	1.47	.001

¹ Joyce et al, 1962

Adherence to Conditioning Exercises

Cardiac Rehabilitation ¹	50% 6 Mo.
Pulmonary Rehabilitation ²	unknown
Rheumatoid and Osteo-Arthritis ³	83% 3 Wk. 63% 6 Mo. 57% 12 Mo.

¹ Oldridge, 1988

² Emerg, 1995

³ Minor et al, 1989

Adherence to Therapeutic Exercises/PT

Physiotherapy for lymphedema ¹	86% 9 Mo.
Raised Leg Exercises for Leg Edema ²	77% 1 Mo.
Pelvic Floor Exercises in Multiple Sclerosis ³	60% 6 Mo.
Therapeutic Exercises for Osteoporosis ⁴	44% 4 Yr.
Psoas Exercises for Lumbar Bone Loss ⁵	42% 3 Yr.

¹ Ko et al, 1988

² Ciocon et al, 1995

³ Yahtera et al, 1989

⁴ Preisinger et al, 1996

⁵ Mayoux-Benhamou et al, 1997

What Do We Ask of Participants?



Participant Adherence Demands

- ◆ Stay on Full Therapeutic/Placebo Regimen
- ◆ Attend Routine Office/Clinic Visits
- ◆ Provide Monitoring/Outcome Data
- ◆ Notification Re: Endpoints
- ◆ Don't Sample Alternative Treatment
- ◆ Stay in Trial to the End

Why Do Participants Join?

- ◆ To Help Others
- ◆ To Help Self
- ◆ Financial Benefit
- ◆ Free Examinations
- ◆ Join Others
- ◆ 'Break Monotony
- ◆ Influenced by Others

Why Do Participants Stay?

- ◆ Medical Monitoring
- ◆ Free Services
- ◆ Personal Reassurance
- ◆ Education/Information
- ◆ Interaction with Others

Burdens (hassles) of Participation

- ◆ Too Busy
- ◆ Adverse Effects
- ◆ Dissatisfied with Perceived Treatment Group
- ◆ Desire Treatment
- ◆ Inconvenient
- ◆ Forgot Portions of Protocol
- ◆ Overlooked
- ◆ "Tired" of Participating
- ◆ Illness in Self or Family
- ◆ Relocation

Impact of The Clinical Protocol

- Frequency of Contact
- Frequency of Visits
- Complexity of the Treatment Program
- Blind (Treatment Regimen/Lab Results)
- Long Term Comprehension of the Protocol
- Duration of the Study

Anticipate Potential

Every Patient Has the Potential To

Be a Drop Out or Poor Adherer



Recognize Risk Conditions

- ◆ Neglected Cohort
- ◆ Missed Visits
- ◆ Declines in Adherence
- ◆ Change in Critical Staff
- ◆ Change in Life Circumstances
- ◆ Study Complaints

Communicate

- ◆ Routinely With The Participant
- ◆ With Other Members of the Research Team
- ◆ With the Accompanying Person

Prevention Strategies

- ◆ Plan Study Contact to Reinforce Continuation
 - Feedback on Status Where Possible
 - Emphasize Value of Participation
 - Provide Positive Communication
 - Education Opportunities Throughout
 - Time with Key Staff
 - Regular Contact
 - Strategies to Address Alerts
 - Reminders

Design Monitoring Strategies for Defined Alerts

- ◆ Track Individual Visit Attendance
 - Missed, Failure to Reschedule
 - Repeated Missed Visits
 - Repeated Rescheduling of Single Visit
- ◆ Track Individual Adherence Over Time
 - Declines
 - Variability

Early Intervention

- ◆ Increased Contact
- ◆ Reinforce Value of Participation
- ◆ Aggressive Rescheduling
- ◆ Problem Solve – Protocol Decline In Adherence

Dealing with Drop Out



Greatest Risk Period --

First 6 Months

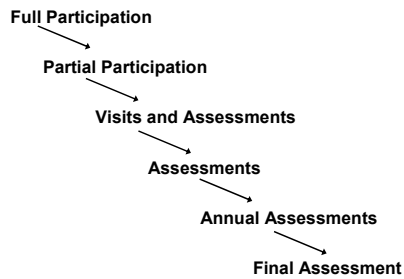
Early Drop Out

- ◆ Ease Into Trial
- ◆ TLC
- ◆ Reassurance
- ◆ Establish Relationship
- ◆ Accommodations

Late Drop Out

- ◆ Aggressive Pursuit
- ◆ Emphasize Value: Others/Self
- ◆ Accommodations
- ◆ Negotiate

NEGOTIATE:



Every Participant is Important!



Phases of Clinical Trial of Relevance to Retention

- ◆ Recruitment
- ◆ Screening
- ◆ Informed Consent
- ◆ Initial Treatment Period
- ◆ Long Term Maintenance

Thank You!
Questions?

