

Recruitment in Yoga Trials: Challenges, Pitfalls, and Strategies for Success

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Learning Objectives

- **To understand:**
 - Common barriers and pitfalls in recruitment
 - Strategies for maximizing recruitment success
 - How to address lagging recruitment





Recruitment: Common Barriers and Pitfalls

Recruitment can be very challenging! *E.g.*

Recent reviews of trial recruitment suggest:

- Only 1/3 meet target goal w/in original time frame
- Up to 90+% extend timeline and/or add sites, etc.
- Many under-enroll
- Up to 20+% never enroll single participant! *E.g.*,
Non-invasive neurostimulation for anterior-tibial
stress fracture

Recruit 2 years=>0 participants





Recruitment: Common Barriers and Pitfalls

Difficulty accruing pts can have serious consequences! E.g. can lead to:

- Major changes in study population, design and ultimately, reduction in study power
- Trial failure, loss of funding, other resources





Recruitment: Common Barriers and Pitfalls

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- Major changes in study population, design and ultimately, reduction in study power
- Trial failure, loss of funding, other resources
- **Enrollment of ineligible or even fictitious participants**





Recruitment Challenges

- *Yet overestimation remains common*
 - ‘Lasagna’s Law’ or the Funnel effect of recruitment
 - Researcher tendency to overestimate pool of pts who
 - Eligible, willing, and able to enroll

Estimated





Recruitment Challenges

- *Yet overestimation remains common*
 - **Funnel effect of recruitment or ‘Lasagna’s Law’**
 - Researcher tendency to overestimate pool of pts who
 - Eligible, interested, willing, and able to enroll
 - Estimated $\leq 10\%$ pts survive recruitment funnel
 - Response rate can be as low as 1%

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Actual





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 - Eligible, interested, willing, and able to enroll
 - Estimated $\leq 10\%$ pts survive recruitment funnel
 - Response rate can be as low as 1%
- *Highlight need to:*
 - Be aware of factors affecting recruitment
 - Do research/planning in advance

Estimated



Actual



Factors Facilitating Recruitment



■ Why do people enroll in trials?

■ Primary reasons

- Potential health benefits
- Physician influence
- Benefit to others

Also: Encouragement by friends/family; free/better care, learn more re condition/management, other benefits (e.g., chance to socialize, participate in fun activity; staff attention; and **incentives**)





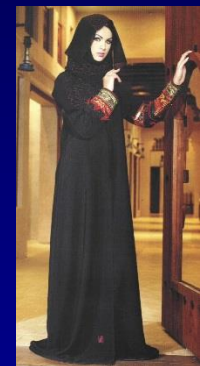
Barriers to Recruitment



■ Why don't people enroll in trials?

■ Participant related factors

- **Demographics** (e.g., age, gender, SES, rurality)
- **Cultural factors, beliefs, values**
 - Religious convictions/affiliations
 - Cultural norms and traditions (clothing, mixing of genders, holidays/religious practices)
 - Skepticism re non-Western approaches
 - Belief that yoga only for young, fit, flexible





Factors Affecting Recruitment



■ Participant related factors, *cont.*

■ Health status and targeted health condition

- E.g. certain cancer populations, those with MDD, those with poorly recognized conditions (e.g., RLS)

■ Negative perceptions re trials/tx assignment

- Bad prior experience
- Fear of being a 'guinea pig'
- Fear of receiving non-preferred tx assignment (CCT)



■ Other psychosocial factors-e.g.,

- Motivation/willingness to change behavior

- Adverse influence of friends, family members, clinicians

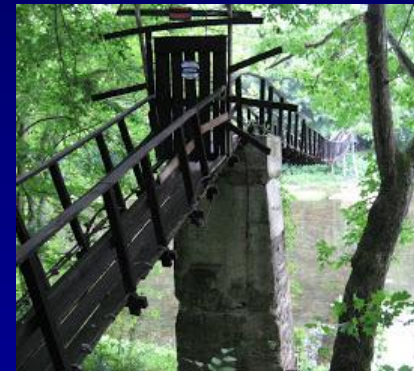


Factors Affecting Recruitment



- **Environmental and Contextual Factors**
 - **Climate/weather**
 - **Availability, perceived efficacy of other tx (e.g., drug/surgical)**
 - *Ex: OA, RLS (vs. preclinical memory loss)*

Factors Affecting Recruitment



- **Environmental and Contextual Factors**
 - Climate/weather
 - Availability, perceived efficacy of other tx (e.g., drug/surgical)
 - Ex: OA, RLS (vs. preclinical memory loss)
 - **Accessibility** (incl distance), **safety of trial site(s)**
 - **Logistical concerns**-e.g.:
 - Transportation, work, caregiving etc. demands
 - Appropriate space in home (home practice)
 - **Competition** for pts with other trials

Factors Affecting Recruitment

- Research/Investigator-Related Factors

- Design-related

- Eligibility criteria too restrictive
- Lengthy trial duration
- Protocol complex, burdensome
- Problematic Intervention/control
- Problematic timing (assessments/intervention)





Factors Affecting Recruitment

Research/Investigator-Related Factors, *cont*

- Poor communication by investigator(s)/staff

E.g., failure to:

- Address pt concerns
- Describe study clearly/provide written info
- Convey expertise, sensitivity =>
↓ credibility, trust

- Condition targeted rare or poorly recognized



Lack of advance recruitment planning/research

Recruitment Planning/Research



- **Understanding & defining your target population**
 - Major determinant of participant pool and ultimately, recruitment/enrollment success!
 - *Factors/Questions to consider*
 - Demographics, geography, culture/beliefs
 - Active online? Use smart phones?
 - Ambulatory? Have transportation?
 - Recruitment catchment sites? Special population?
 - Health status? Typically have a caregiver?
 - Targeted condition:
 - Existing tx? Well-recognized? Common?



Recruitment Planning/Research



- Defining the Target Study Population, cont
 - *Eligibility criteria:*
 - Focus on those central to your study goals, consistent with outcomes, pt safety, and feasibility
 - *If too restrictive=>*
 - Significantly reduce participant pool
 - Discourage potential participants who might benefit
 - Compromise recruitment
 - *If too broad, may increase recruitment but =>*
 - Reduce ability to detect an effect
 - Render findings hard to interpret

Recruitment Planning/ Research, *cont.*

Pilot studies very valuable!

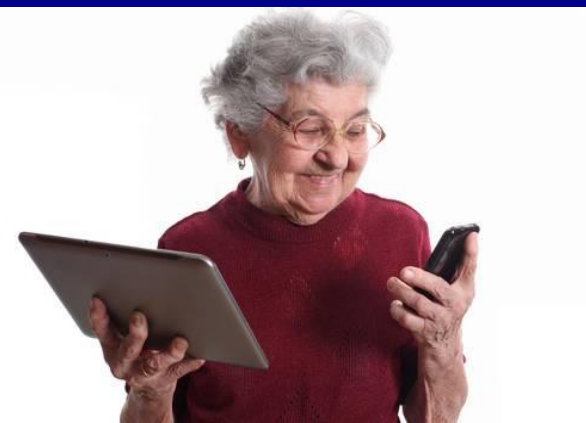
E.g., Can help determine:

- Prevalence of target condition
- Likely participant characteristics
- Recruitment feasibility, rates
- Optimal recruitment strategies: Often differ by
 - Site and geographic location, target population, etc
- *Modifications* needed in:
 - Language, incentives
 - Study design, site, timing, etc
 - Intervention delivery





Recruitment Strategies: What works?





Recruitment Strategies

Often multiple strategies necessary. *E.g.,*

- Letters of invitation using existing records, lists

PROs:

Often low cost, can be generated using *existing databases*

Can be especially useful for:

- Burdensome conditions for which tx inadequate
- Rare conditions/hard to reach populations
- ‘Captive’ populations

CONs:

- Often low yield
- HIPAA, medical records concerns
- No info on willingness to enroll



Recruitment Strategies, *cont*

- **Provider referrals**

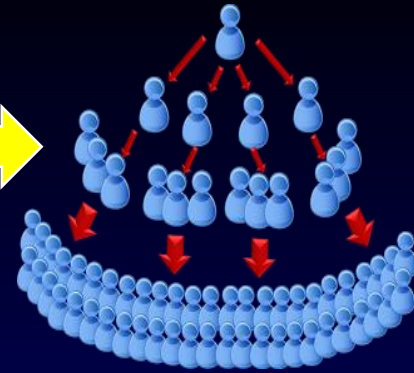
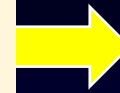
- **BUT** even when pledged, those referred often few
- Engaging providers as investigators can ↑ yield
E.g., authorship on publications, etc.

Designation of 'study champions'

- **Flyers and brochures** posted in clinic waiting rooms, offices, churches, stores, etc.
- **Media**, incl:
 - Listservs, social media, websites
 - Newsletters, radio, TV
- **Health fairs, socials, other gatherings**



Recruitment Strategies, *cont*

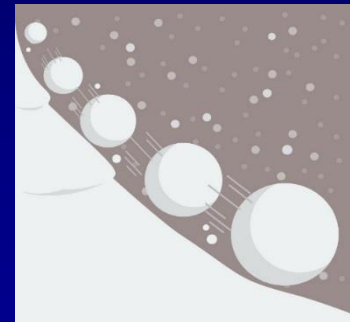


- **WORD of mouth**

- E.g., Women's Health, Yoga and Education Study (WHYES)

Can => effective ***Snowball Sampling***

Esp useful in community-based trials



Another reason to maintain good relations with community and with participants!

Recruitment Strategies, *cont*



- **Presentations** to church, physician, support, and other provider and lay groups

Many benefits – may:

- Enhance relations with both professional and lay communities
 - Increase study visibility
 - ↑ recruitment through word of mouth, referrals, etc.
 - Aid in establishing collaborations and in creating new opportunities
- **Incentives** always helpful, even if small – e.g.
 - \$\$, gift cards, candy; ‘Free’ services, equipment
 - Lottery, prize(s)





Lagging Recruitment: What to Do?



Recruited

Enrolled



“What if we don’t change at all ...
and something magical just happens?”

Approaches to Lagging Recruitment: What to do?



1) Broaden catchment area/Add new pt sources:

Expand locations/settings from which recruit

- *Ex:* meditation for memory loss and caregiver trial

2) Broaden recruitment strategies/personnel

- Advertise using additional venues
- Engage community members/clinicians/stakeholders
 - *Ex:* Yoga for RLS; Yoga for back pain in Veterans (Saper, PI)
- Add recruitment personnel with special skills/access
 - *Ex:* **WHYES:** minority recruitment specialist

Approaches to Lagging Recruitment: What to do?



3) Extend time allocated for recruitment

BUT: If a group intervention, may lose pts due to time lag

4) Relax eligibility criteria

- Can actually ↑ both pt nos. and generalizability
- **BUT:** Important that not compromise study design/aims
- May alter outcomes, # adverse events, etc.

Ex: Trial of meditation for adults with early AD and their caregivers, relax criteria to include MCI

Approaches to Lagging Recruitment: What to do?



5) Accept reduced number of participants:

BUT: ↓ power may diminish ability to detect an effect

Ex: Yoga and RLS trial

6) Recycling of participants (repeat testing of screen failures)

- **BUT:** May sometimes lead to inclusion of ineligible pts
- May be useful, e.g., if eligibility criteria incl requirements that likely to change over time for given pt:
 - *Ex:* Stable on meds for 3 months; not in study in prior 30 days, not practiced yoga for 1 year, etc.

Approaches to Lagging Recruitment: What to do?



7) Add another study site

- Can dramatically increase participant pool and recruitment success **BUT**
- **Many Considerations:**
 - *Resources:* Can you afford to add a site?
 - *Logistics:* Feasible to add a site? Location suitable?
 - *Investigative team:* Adequate? Who will train personnel, oversee study, screen/randomize pts, conduct assessments, etc.?
 - *Intervention:* Can implement study intervention as planned in new site?
 - *Approvals:* Will funding bodies/IRB allow? Central IRB?
- **Essential to plan carefully in advance!!**

Recruitment, cont.

Additional Tips



- **Planning critical**
 - Strategies in place, ideally other pt sources in reserve if recruitment lags
 - Liaisons established with clinics, schools, churches, and/or other sites, etc. where planning to recruit and permissions obtained- Ideally, with provider etc. buy-in
 - Adequate personnel, time, resources
- **Good communication skills, relationships w/pts** essential to establish trust, cooperation





WRAP UP

Recruitment challenges and strategies





Recruitment Challenges



- **Many factors can affect recruitment**
 - Participant-related. *E.g.*
 - Demographics, Culture/Beliefs, Fears/concerns
 - Environmental/Contextual. *E.g.*
 - Other tx, logistical/accessibility concerns, competition
 - Research-related. *E.g.*
 - Eligibility criteria, burden, health condition, communication
- **Multiple reasons for participation. *E.g.:***
 - Health benefit/care/knowledge; Benefit to others
 - Influence of clinician/others
 - Incentives



Recruitment Strategies



- Advance planning/research important!
- Pilot studies very valuable!
- Often multiple approaches needed
 - Media venues; provider referrals/letters; study champions
 - Word of mouth; Presentations; Incentives



Awareness of pt concerns, exc communication essential

- Several approaches to lagging recruitment
 - ↓ Pts; ↑ time, strategies, settings; relax criteria
 - ‘Recycling’; adding additional recruitment site(s)

Need to make it as easy and attractive as possible for your target population to participate!

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Study Population

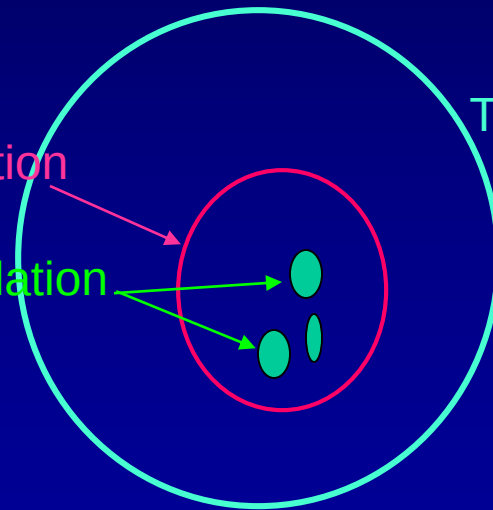
- **Final enrolled population**
 - = **Available + Eligible + Willing**
 - Generally *nonrandom* sample of target population
 - Generally small % eligible participants

Reference population

Accessible population

Sample population

Target pop



Recruitment Strategies: What works?



- Recruitment strategies and procedures will depend on:
 - Resources, logistics, time
 - Design, location(s), size, length, setting(s) of trial
 - Target population-related factors, including, e.g.:
 - Health characteristics and catchment area (e.g., clinical vs. non-clinical, hospital, primary care, schools, etc)
 - Cultural and demographic factors
 - Interest and motivation
 - Pt experience/perceptions re research



Recruitment, cont.

Additional Tips



- **Planning critical**
 - Strategies in place, ideally other pt sources in reserve if recruitment lags
 - Liaisons established with clinics, schools, churches, and/or other sites, etc. where planning to recruit and permissions obtained- Ideally, with provider etc. buy-in
 - Adequate personnel, time, resources
- **Good communication skills, relationships w/pts** essential to establish trust, cooperation
- **Aggressive recruiting** (arm-twisting) may lead to:
 - Enrolling non-compliant participants=>
 - Ultimately, compromised trial





Barriers to Recruitment



■ Why *don't* participants enroll in trials?

■ Participant related factors

- Demographics (e.g., age, gender, SES, rurality)
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