

Recruitment: Challenges and Strategies

Sonika Bhatnagar, MD, MPH
Division of General Academic Pediatrics
University of Pittsburgh School of Medicine
Children's Hospital of Pittsburgh of UPMC



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Problem

Despite general and pediatric-specific challenges to recruitment in randomized controlled trials, a paucity of evidence exists on effective recruitment strategies and assessment tools to reliably enhance recruitment.



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Challenges Randomized Controlled Trials (RCT)

Under-recruitment (50-63%)

- Inadequate sample size
- Type II error
- Reduced statistical power
- Poor generalizability
- Demoralized staff
- Uneven workloads between participating sites

Sources: Treweek S. Cochrane Database Syst Rev. (2010); Mapstone J. Cochrane Database Syst Rev. (2007)



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Challenges Randomized Controlled Trials (RCT)

50% RCTs require extensions, resulting in:

- Increased cost
- Delay in implementation of effective interventions
- Risk of study closure
- Risk of opting for less robust study design

Source: Pighills A. Journal of Clinical Epidemiology (2009)



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Barriers to Participation Clinician Concerns

- Time constraints
- Space constraints
- Lack of staff and training
- Loss of professional autonomy
- Concern for patients
- Difficulty with consent process
- Lack of rewards and recognition

Sources: Mapstone J. Cochrane Database Syst Rev. (2007); Spaar A. BMC Med Res Methodol. (2009)



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Barriers to Participation Patient Concerns

- Additional procedures, appointments, travel, and cost
- Preference for a particular treatment
- Concern about biased information and consent

Source: Mapstone J. Cochrane Database Syst Rev. (2007)



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Barriers to Participation Patient Concerns (continued)

Diverse populations

- Mistrust
- Lack of awareness of the importance of research
- Lack of community engagement and involvement
- Lack of tangible benefits from participation
- Economic & time constraints
- Transportation

Source: Rajakumar, K (2014)



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Pediatric Randomized Control Trials Parent Challenges

Parental

- Sense of responsibility
- Fear of regretting decision
- Need to protect child outweighs altruism
- Perception of uncertainty vs. hope
- Relationship with pediatrician influences decision

Source: Shilling V. BMC Med Ethics (2009)



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Effective Strategies to Improve Clinician Participation

- Develop trusting relationship with clinician (office visits)
- Foster positive attitude of clinicians towards research
- Stimulate intellectual curiosity
- Minimize workload: create one-step referral process

Sources: Raynor HA. Int J Pediatr Obes. (2008); Mainous AG. J Natl Med Assoc. (2008); Graffy J. Fam Pract. (2009); Source: Watson JM. BMC Med Res Methodol. (2006)



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Effective Strategies to Improve Participation (continued)

- Ask a clinically relevant and timely research question
- Have a respected investigator and dedicated trial manager
- Make the clinician proud to be part of the research team
- Educate clinician on research and potential patient benefits
- Emphasize trial safety and relevance
- Emphasize trial is in-line with existing clinical practice
- Emphasize needs of patients being well served
- Provide direct access to PI via cell phone at all times
- Foster consultation and open communication

Sources: Raynor HA. Int J Pediatr Obes. (2008); Mainous AG. J Natl Med Assoc. (2008); Graffy J. Fam Pract. (2009); Campbell MK. Health Technol Assess. (2007); Raftery J. Trials. (2009)



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Effective Strategies to Improve Participant Interest

Use culturally and linguistically appropriate approaches

- Preferred language of family, interpreters
- Easy to understand print, media (health literacy)
- Community or parent advisory board engagement

Cover costs for travel, parking, transportation

Provide monetary incentives for patients

- Ethical issues:
 - Undue inducement
 - Taking advantage of economically vulnerable population

Sources: Raynor HA. Int J Pediatr Obes. (2008); Mainous AG. J Natl Med Assoc. (2008); Graffy J. Fam Pract. (2009); Source: Watson JM. BMC Med Res Methodol. (2006)



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INEffective Strategies

Publicity: Expensive with No statistically significant impact

- Newspaper, bus, internet, TV, video
- Pre-enrollment: personalized letter, postcard, message on voicemail

Financial incentives for clinicians

- Potential negative impact

Alteration of study design

- Patient preferred treatment vs. randomization
- Surveillance vs. placebo

Source: Pighills A. Journal of Clinical Epidemiology (2009); Mapstone J. Cochrane Database Syst Rev. (2007); Raftery J. Trials (2009); Watson JM. BMC Med Res Methodol. (2006)



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Recommendations Investigator and Clinician

Build relationships and trust

- Most critical
- Statistically significant
- Cost-effective

Foster clinicians' sense of pride and contribution

Minimize clinician workload

- Delineate pediatrician's role
- Recruitment and consent done by research team



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Investigator and Clinician: Build Relationships and Trust

Conduct site visits

- Target “high yield” clinicians
- Provide education on diagnosis and related research
 - Review relevant publications and recommendations
 - Stimulate intellectual curiosity
- Emphasize clinical relevance and timeliness of research
- Stress trial safety and potential benefits to study participants, including needs of participants well-served
- Emphasize Investigator availability for research *and* non-research clinical questions



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Investigator and Clinician: Build Relationships and Trust

Conduct site visits, continued

- Provide brief eligibility criteria and one step contact information
- Provide useful supports
 - Information to display on smart phones
 - Flash drives with study related resources
 - Posters/brochures for lunch and conference rooms, education boards, and parent waiting rooms



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Investigator and Clinician: Build Relationships and Trust

Conduct site visits, continued

- Engage, obtain buy-in from office managers, nurses, medical assistants and all involved
 - Incorporate the medical home within the research home
 - Create a team-of-care environment
 - By definition, a team is a group of people working together to accomplish a common goal
 - Every person who interacts with the family of the eligible child is a part of the research team
 - Schedulers, registration, medical trainees, clinical and diagnostic providers, administrative staff and coordinators, and division chairs
 - An effective team can achieve incredible results



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Build Relationships and Trust

- Screen daily for prompt clinician notification
- Close the loop by notifying clinician of family's decision to participate or not participate
- Provide clinician with regular participant trial updates
- Build name recognition as an expert while providing education
 - Speak at Grand Rounds, local society meetings, in-services, and noon teleconferences/conferences
 - Write articles in clinician/hospital newsletters and publications
 - Create a listserv as a resource for providing clinicians with a protocolized summary of key evidence and clinical applicability from latest relevant publications with the reference provided



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Investigator and Clinician

Foster clinicians' sense of pride and contribution

- Send "thank you" notes to participating clinicians
- Use listserv to provide interim updates and project publications using the protocolized summary previously detailed

Minimize clinician workload. Provide:

- Single phone number to reach PI, 24/7
- One step process for referrals
- A "concierge service" to assist in scheduling research- and non-research related imaging or other appointments
- 1-2 points for clinician use to introduce research to family



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Recommendations: Investigator and Families of Eligible Children

1. Promptly contact while concern is acute
2. Incorporate culture
3. Be respectful and accommodating
4. Go above and beyond research



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Investigator and Families of Eligible Children

1. Promptly contact family while concern is acute
 - Have initial discussion within 1-2 days of diagnosis
 - Lead introduction with reference to trusted clinician with whom PI has already spoken
 - Place follow-up call for decision within 1 to 2 days
 - Encourage questions
 - Provide 24/7 access to PI
 - Refer to study-specific comprehensive websites, videos, and/or brochures



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Investigator and Families of Eligible Children

2. Incorporate culture

- Train investigators in cultural competence and health disparities
- Have a multilingual PI and team
- Partner with families and/or community members to develop protocol, materials
- Provide materials in family's primary language
- Involve relevant decision makers: Invite family-identified others to be a part of the discussion (e.g., other parent, grand-parent, family advisor, clan leader, spiritual guide)



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Investigator and Families of Eligible Children

3. Be respectful and accommodating

- Avoid contacting families on holidays or on their days of worship (Saturdays, Sundays)
- Do not call a family more than 2-3 times
- Provide meal tickets and reimbursement for transportation and parking
- Offer flexible enrollment hours
- Ensure little to no wait times for research appointments



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Investigator and Families of Eligible Children

4. Go above and beyond research

- Provide "concierge services":
 - assist in scheduling diagnostic tests
 - coordinate subspecialist or well care visits with research appointments
- Meet parents at non-study tests that are diagnosis related and standard of care; contact families immediately with test results
- Offer options of home visits and office and hospital locations



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Mary Ann Haralam, CRNP
Diana Kearney, RN, CRCC*
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References

- [Bill-Axelsson A, Christensson A, Carlsson M, Norlén BJ, Holmberg L](#). Experiences of randomization: interviews with patients and clinicians in the SPCG-IV trial. *Scand J Urol Nephrol*. 2008;42(4):358-63.
- [Shilling V, Young B](#). How do parents experience being asked to enter a child in a randomised controlled trial? *BMC Med Ethics*. 2009 Feb 16;10:1.
- [Ravnor HA, Osterholt KM, Hart CN, Jelalian E, Vivier P, Wing RR](#). Evaluation of active and passive recruitment methods used in randomized controlled trials targeting pediatric obesity. *Int J Pediatr Obes*. 2008 Dec 11:1-9.
- [Dolan LA, Sabesan V, Weinstein SL, Spratt KF](#). Preference assessment of recruitment into a randomized trial for adolescent idiopathic scoliosis. *J Bone Joint Surg Am*. 2008 Dec;90(12):2594-605.
- [Mainous AG 3rd, Smith DW, Geesey ME, Tilley BC](#). Factors influencing physician referrals of patients to clinical trials. *J Natl Med Assoc*. 2008 Nov;100(11):1298-303.
- [Graffy J, Grant J, Boase S, Ward E, Wallace P, Miller J, Kinmonth AL](#). UK research staff perspectives on improving recruitment and retention to primary care research; nominal group exercise. *Fam Pract*. 2009 Feb;26(1):48-55.
- [de Salis J, Tomlin Z, Toerien M, Donovan J](#). Using qualitative research methods to improve recruitment to randomized controlled trials: the Quartet study. *J Health Serv Res Policy*. 2008 Oct;13 Suppl 3:92-6.
- [Baquet CR, Henderson K, Commiskey P, Morrow JN](#). Clinical trials: the art of enrollment. *Semin Oncol Nurs*. 2008 Nov;24(4):262-9.



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References

- [Dormandy E, Kavalier F, Logan J, Harris H, Ishmael N, Marteau TM; SHIFT research team](#). Maximising recruitment and retention of general practices in clinical trials: a case study. *Br J Gen Pract*. 2008 Nov;58(556):759-66, i-ii.
- [Donovan JL, Lane JA, Peters TJ, Brindle L, Salter E, Gillatt D, Powell P, Bollina P, Neal DE, Hamdy FC; Protect Study Group](#). Development of a complex intervention improved randomization and informed consent in a randomized controlled trial. *J Clin Epidemiol*. 2009 Jan;62(1):29-36.
- [de Salis J, Tomlin Z, Toerien M, Donovan J](#). Qualitative research to improve RCT recruitment: issues arising in establishing research collaborations. *Contemp Clin Trials*. 2008 Sep;29(5):663-70.
- [Galbreath AD, Smith B, Wood P, Forkner E, Peters JI](#). Cumulative recruitment experience in two large single-center randomized, controlled clinical trials. *Contemp Clin Trials*. 2008 May;29(3):335-42.
- [Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, Entwistle V, Garcia J, Roberts I, Grant A, Grant A; STEPS group](#). Recruitment to randomised trials: strategies for trial enrollment and participation study. The STEPS study. *Health Technol Assess*. 2007 Nov;11(48):iii, ix-105.



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References

- [Mapstone J, Elbourne D, Roberts I. Strategies to improve recruitment to research studies.](#) *Cochrane Database Syst Rev*. 2007(2):MR000013.
- [Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: a review of randomised controlled trials.](#) *BMC Med Res Methodol*. 2006;6:34.
- [Pighills A, Torgerson DJ, Sheldon T. Publicity does not increase recruitment to falls prevention trials: the results of two quasi-randomized trials.](#) *Journal of Clinical Epidemiology*. 2009 May 25.
- [Raftery J, Kerr C, Hawker S, Powell J.](#) Paying clinicians to join clinical trials: a review of guidelines and interview study of trialists. *Trials*. 2009 Mar 10;10:15.
- [Spaar A, Frey M, Turk A, Karrer W, Puhan MA.](#) Recruitment barriers in a randomized controlled trial from the physicians' perspective: a postal survey. *BMC Med Res Methodol*. 2009 Mar 2;9:14.
- [Treweek S, Mitchell E, Pitkethly M, et al.](#) Strategies to improve recruitment to randomised controlled trials. *Cochrane Database Syst Rev*. 2010(1):MR000013.



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