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Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Topic 7: Pilot and Feasibility Testing

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Collaboratory ePCT Training Workshop

Overview

- Importance of piloting the intervention to be embedded (ePCTs can be “messy”)
- Special feasibility considerations for ePCTs
- Context, capabilities & challenges of the partnering HCS
- Piloting key elements of the intervention
- Case study: The SPOT Demonstration Project
- Ensuring trial is ready to launch

ePCTs are not efficacy trials

- ePCTs bridge research into clinical care
- Intervention is integrated into a real-world healthcare setting & is usually compared to usual care
- Primary goal is to gather generalizable information to inform HCS decision-makers
- Special feasibility considerations
  - Establish close partnerships with HCS personnel
  - Test & validate EHR data collection & extraction methods
  - Assess how well the intervention can be integrated into the clinical workflow as seamlessly as possible
  - Identify local champions at each study site

Build the HCS partnership during the pilot study

- Is the intervention aligned with the healthcare priorities of the HCS?
- Has the study team established effective partnerships with HCS leadership, clinicians, providers, and IT staff?
- Readiness of the partner HCS
  - Are extra resources needed to support the intervention, identify participants, and extract necessary data?
  - How many sites are available to fully participate?
  - How much provider training will be needed, and can training utilize existing HCS infrastructure?
- If the intervention proves successful, what adaptations would be needed to implement it into other healthcare settings?

Aspects of feasibility that can be piloted

- Verify that the eligible target population can be identified via the EHR or other planned methods
- Test any phenotypes needed for sample identification
- Validate data collection and extraction methods & test data sample for quality & accuracy
- Coordinate processes with local champions
- Test the training materials for frontline providers & staff

Aspects of feasibility that can be piloted

- Evaluate informed consent materials and processes
- Test appropriateness & usability of study toolkits or other materials
- Evaluate whether fidelity/adherence measures can be achieved to justify the full-scale ePCT
- If cluster randomization is involved, collect data to confirm estimate of intraclass correlation (ICC) for power calculations

Aspects of feasibility that can be piloted

Use what you learn to design the ePCT

How to quantify feasibility for pilot study aims

Eligibility

Recruitment

Randomization

Adverse events

Retention

Missing data

Intervention fidelity

NEXT: Examples of pilot study aims that quantify feasibility

Example 1

Demonstrate effective recruitment and retention, which is defined as the ability to recruit an average of 10 patients per month per site and retain 80% of participants for final data collection at 6 months

Example 2

Determine whether the intervention can be delivered with reasonable feasibility, defined as 70% of the enrolled participants engage in the intervention

Example 3

Demonstrate ability to collect primary outcomes and minimize missing data to less than 5% of primary outcome measures

Case study: SPOT

- Feasibility illustration from the Suicide Prevention Outreach Trial
  - Dr. Greg Simon, Principal Investigator
  - An NIH Collaboratory Demonstration Project in UH3 phase

Resource: SPOT Demonstration Project webpage in the Living Textbook

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Pilot-testing Interventions in Pragmatic Trials: SPOT Case Study

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Suicide Prevention Outreach Trial

- Pragmatic trial of outreach programs to prevent suicide attempt
- Automatically enroll outpatients reporting frequent thoughts of death or self-harm on routine depression questionnaires
- Randomly assigned to continued usual care or one of 2 outreach programs
- Analysis by intent to treat, regardless of intervention uptake or adherence

SPOT interventions

- Risk assessment and care management
  - Systematic outreach to monitor risk of suicide attempt
  - Risk-based pathways for follow-up care
  - Outreach to maintain engagement in outpatient care
- Dialectical behavior skills training
  - Specific DBT skills shown to reduce risk of suicide attempt
  - Interactive online program for self-guided skills training
  - Supported by outreach from online coach
- Common to both
  - Outreach for up to 1 year
  - Intended as supplements to existing treatment
  - Accommodate different levels of participant engagement
- Each program was “moderate leap” from previous research

Intervention process

- Up to 3 rounds of invitation
  - Invitation by online messaging with option of phone follow-up
  - Participants free to decline at any time
  - Cease invitation if no response after three tries
- Care management
  - Outreach via messaging with option of phone follow-up
  - Frequency depending on risk level and engagement in care
  - As-needed coordination with treating outpatient providers
- Skills coaching
  - Free use of online program
  - Reinforcement messages for those using program
  - Outreach/reminder messages to those overdue

A priori limits on interventions

- Total cost no more than $100 per person
- Centralized delivery by online messaging (via EHR portal)
- Delivered by masters-prepared mental health providers
- Scalable to full health system population

Pilot study process

- 3 waves of pilot testing ~40 in each wave
- Full implementation of invitation process
- Care management/coaching limited to 3 months
- No ascertainment of outcomes

Pilot study questions

- Expected rate of initial engagement
- Incremental gain with additional waves of invitation
- Optimal wording of invitation messages
- Proportion requiring telephone follow-up

What we learned/changed

- Gain from 3rd wave of invitation is worth the effort
- Initial language describing the program was confusing
- Approximately 30% of invites require telephone follow-up
- Uptake rate tops out at 40%-45%

What we didn't do

- Attempt to assess intervention impact or effectiveness
- Select participants for higher likelihood of participation
- Offer telephone services as alternative to outpatient care
- Extend beyond 3 cycles of invitation
- Personalize program to preferences or concerns of providers or clinics

In the end, it's about

- Avoiding silly mistakes
- Maximizing acceptability
- Maintaining affordability
- Remembering scalability

Ensuring trial readiness

- Troubleshooting & iterative testing
- Flexibility to accommodate local conditions & changes over time
- Continuous engagement with HCS
- Readiness criteria checklist
  - Recruitment plans are finalized
  - Ethical/regulatory aspects are addressed
  - Intervention is fully developed & finalized
  - Data collection methods are adequately tested
  - Budget is realistic & feasible

Readiness checklist

Milestone	Completed
Recruitment plans are finalized	
All sites identified (documentation of site commitment)	
Methods for accurately identifying participants validated	
All agreements for necessary subcontracts in place	
Ethical/regulatory aspects are addressed	
Coordinated IRB oversight in place	
Finalized plans for informed consent or waiver of informed consent	
Finalized data and safety monitoring plan	
Intervention is fully developed and finalized	
Finalized intervention (including materials and training at sites) ready for site implementation	
Finalized protocol is IRB approved (informed consent and data collection forms, if applicable)	
Data collection methods are adequately tested	
Validated methods for the electronic health record information	
Validated study surveys, interviews, or other data collection modes	
Demonstrated quality assurance and harmonization of data elements across healthcare systems/sites	
Statistical and data analysis methods have been adequately developed	
Budget is realistic and feasible	

Source: Study Startup chapter in the Living Textbook **www.rethinkingclinicaltrials.org**

Important things to know

- Pilot testing of the ePCT methods increases likelihood of completing the trial, prevents silly mistakes
- You need a biostatistician in the pilot/feasibility stage
- “Process issues” can derail the ePCT
- Use the pilot study to maximize acceptability, maintain affordability & consider scalability of your intervention

Important things to do

- Conduct a pilot or feasibility study of the ePCT intervention(s)!
- Work with a great biostatistician
- Develop a partnership approach to working with your HCS
- Identify local champions for all of your sites
- Anticipate, identify & make a plan to address changes in the HCS

Think of 2 aspects of your trial that are essential to pilot

2 min

4 min