Pilot and Feasibility Testing

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Learning goals

• Identify why it’s important to do a pilot study to maximize acceptability, maintain affordability, and consider scalability of the ePCT intervention

• Learn key approaches to evaluating the capabilities of the partner health system and testing key elements of the intervention
Important things to know

- Pilot testing the ePCT methods increases likelihood of completing the trial and can prevent 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, and consider scalability of your intervention.
ePCTs are not efficacy trials

- ePCTs bridge research into clinical care
- Intervention is integrated into real-world healthcare settings
- Involves streamlined data collection
- Pragmatic does not always mean low cost
During the pilot phase

- Establish close partnerships with health system personnel
- Test and validate EHR data collection and extraction
- Assess how well the intervention can be integrated into the clinical workflow
- Identify multiple local champions at each study site
Build partnerships

- Is the intervention aligned with the priorities of the partner health system?
- How ready is the partner?
  - 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 use existing health system infrastructure?
- If the intervention proves successful, what adaptations would be needed to implement it in other healthcare settings?
Aspects of feasibility that can be piloted

- Verify that target population can be identified via the EHR
- Test data sample for quality & accuracy
- Test appropriateness & usability of study toolkits or other materials
- Test phenotypes needed for sample identification
- Coordinate processes with local champions
- Evaluate informed consent materials
- Validate data collection & extraction methods
- Test the training materials for frontline providers & staff
- Evaluate whether fidelity/adherence measures can be achieved to justify the full-scale ePCT

Use what you learn to design the ePCT
If cluster randomization is involved, collect data to confirm estimate of intraclass correlation (ICC) for power calculations.
Quantify feasibility for pilot study aims

- Eligibility
- Recruitment
- Randomization
- Adverse events
- Retention
- Missing data
- Intervention fidelity

*Keep in mind realistic targets for the study’s patient population*
Quantifying example 1

Demonstrate effective recruitment and retention, which we define 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.
Quantifying example 2

Determine whether the intervention can be delivered with reasonable feasibility, which we define as 70% of the enrolled participants engage in the intervention.

Determine whether the smoking cessation intervention can be delivered with reasonable feasibility, which we define as 20% of the approached participants engage in the intervention.
Quantifying example 3

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

Demonstrate ability to collect primary outcome of depression symptoms (patient reported) and minimize missing data to less than 10% of primary outcome measures.
Ensuring trial readiness

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

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

• Avoiding silly mistakes
• Maximizing acceptability
• Maintaining affordability
• Remembering scalability
Important things to do

- Conduct a pilot or feasibility study of the intervention to inform the final design of the ePCT
- Work with a great biostatistician and an informatician (if needed)
- Develop a partnership approach to working with your healthcare system
- Identify multiple local champions for all your sites
- Anticipate, identify, and make a plan to address changes in the healthcare system
Assessing Feasibility: Pilot Testing

www.rethinkingclinicaltrials.org