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# Trials of Non-pharmacological Interventions

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# Financial Disclosures

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- Employee
  - County of Los Angeles, Department of Health Services, Harbor-UCLA Medical Center
  - David Geffen School of Medicine at UCLA
  - Los Angeles Biomedical Research Institute
  - Berry Consultants, LLC
- Special Government Employee
  - Food and Drug Administration/CBER
- Support from
  - National Institutes of Health/NINDS
  - National Institutes of Health/NHLBI
- Other consulting
  - Octapharma

# Drugs vs Devices vs Behavioral

	Drugs	Devices	Behavioral
Preclinical	<ul style="list-style-type: none"> <li>• Mechanism &amp; target engagement</li> <li>• Safety</li> </ul>	<ul style="list-style-type: none"> <li>• Engineering &amp; materials</li> <li>• Animal studies</li> </ul>	<ul style="list-style-type: none"> <li>• Not applicable?</li> </ul>
Early Clinical	<ul style="list-style-type: none"> <li>• Mechanism &amp; target engagement</li> <li>• Mechanistic efficacy (e.g., “phase II endpoint”)</li> <li>• Safety (common)</li> <li>• Dose finding</li> </ul>	<ul style="list-style-type: none"> <li>• Device refinement (e.g., software version)</li> <li>• Standardization of technical/clinical use</li> <li>• “Knobology” &amp; adjustable settings</li> </ul>	<ul style="list-style-type: none"> <li>• Qualitative methods</li> <li>• Standardization of intervention</li> <li>• “Fixed” vs tailored treatments</li> <li>• Development of outcome measures</li> <li>• Mixed methods</li> </ul>
Confirmatory	<ul style="list-style-type: none"> <li>• Clinical efficacy</li> <li>• Safety (rare)</li> <li>• Large N</li> <li>• Subgroup challenges</li> </ul>	<ul style="list-style-type: none"> <li>• Device effect</li> <li>• Device AEs</li> <li>• Small/moderate N</li> </ul>	<ul style="list-style-type: none"> <li>• Patient factors</li> <li>• Provider factors &amp; generalizability</li> <li>• Moderate N</li> <li>• Mixed methods</li> </ul>
Key Tasks and Considerations	<ul style="list-style-type: none"> <li>• Dose finding</li> <li>• Placebo vs active controls</li> </ul>	<ul style="list-style-type: none"> <li>• Device settings &amp; versions</li> <li>• Sham procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Balancing intensity of arms</li> <li>• Standardization</li> </ul>