# From Pilot to R01:
# How Pilot Studies Pave the Way to Funding Success
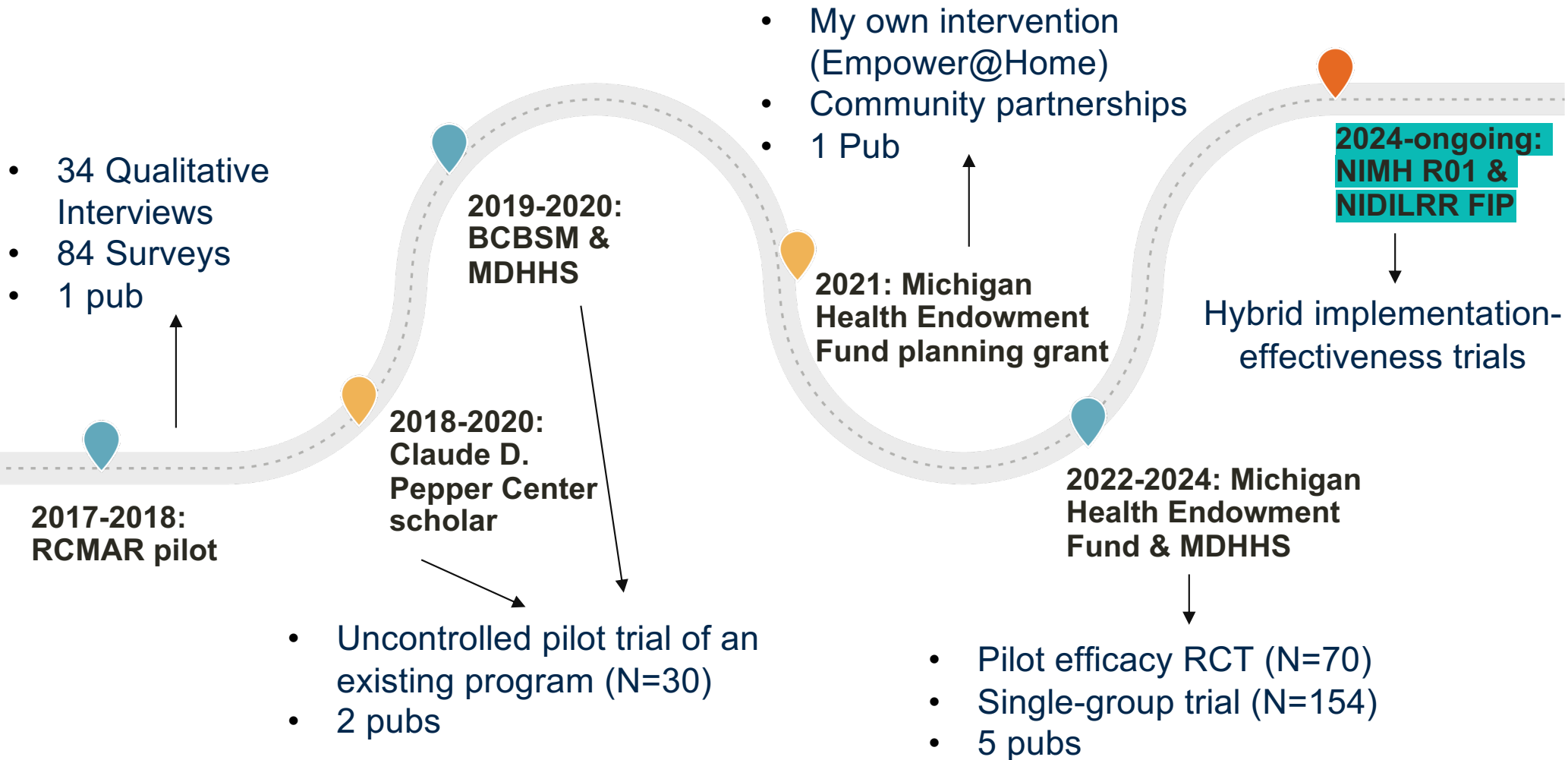
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# Agenda

- My journey: From pilots to R01

- Role of pilot studies

- Designing pilots that build reviewer confidence

- Lessons learned & practical tips

# My background

- **Research focus:** Developing, evaluating, and implementing digital mental health interventions in community social service settings — non-specialty, non-traditional settings.

- **Methods training:** Quantitative data analysis (secondary data analysis of large surveys)

- 34 Qualitative Interviews
- 84 Surveys
- 1 pub

**2017-2018: RCMAR pilot**

**2019-2020: BCBSM & MDHHS**

**2018-2020: Claude D. Pepper Center scholar**

- Uncontrolled pilot trial of an existing program (N=30)
- 2 pubs

- My own intervention (Empower@Home)
- Community partnerships
- 1 Pub

**2021: Michigan Health Endowment Fund planning grant**

**2024-ongoing: NIMH R01 & NIDILRR FIP**

Hybrid implementation-effectiveness trials

**2022-2024: Michigan Health Endowment Fund & MDHHS**

- Pilot efficacy RCT (N=70)
- Single-group trial (N=154)
- 5 pubs

# Pilot studies: Purposes

- Feasibility

- Acceptability

- Refinement

- Preliminary signals

- Implementation readiness

- Capacity building

# Pilot studies: Pitfalls & Myths

- Treating pilots as small RCTs

- Overemphasizing hypothesis testing instead of decision-making for next steps

- Ignoring alignment between pilot aims and future grant goals

- You need a large sample to be convincing

- Pilot studies are too small to publish

# The paradox of small RCTs

| Feature | Consequence |
|---|---|
| Small N → unstable variance | Inflated or deflated effects by chance |
| Random imbalance in groups | Skewed outcomes despite randomization |
| High researcher enthusiasm | Hawthorne effects, extra support |
| Selective or motivated participants | Optimistic early results |
| Contextual novelty | "Startup effect" that fades in routine use |

# What reviewers want to see instead

- Feasibility metrics: strong retention, recruitment

- Clear acceptability data

- Consistent trends across measures

- Plausibility of mechanisms of change

- Reasonable interpretation: "promising but preliminary" or "encouraging signal" > "proof that it works" or "demonstrated efficacy"

# Design pilots that
# build reviewer confidence

Reviewer's mindset: feasibility, readiness, capability, and logical next step.

- Make aims decision-oriented: e.g., "to determine whether recruitment procedures yield ≥70% completion."

- Align measures and outcomes with the future R01 design.

- Collect pilot data that reviewers can extrapolate: recruitment rate, adherence, fidelity, preliminary signal, implementation logistics.

- Build a clear chain of logic across studies ("This pilot informed X design choice in our R01").

# Lessons learned & Practical Tips

- Be strategic and balance rigor with realism

- Publish feasibility and process papers

- Seek internal and small foundation grants strategically

- Know when you are ready to scale up

# Thanks!

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