Clinical Trails for Generative AI Menal Health Interventions.

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Disclosures

- Paid scientific consultant:
  - Benchmark Health
  - Slingshot
  - King County Behavioral Health Research Division

Overview

- Types of Mental Health Generative AI Chatbots.
- The Clinical Trial Pipeline
- Considerations for Clinical Trials of Gen AI

Gen AI mental health uses

- Wellness
- Psychoeducation
- Decision Support
- Training
- Intervention support
- Treatment

Clinical trial pipeline







Target Identification → Proof of concept → Efficacy/safety → Effectiveness → Implementation → Integration → Policy and financing

Images from Flaticon

A word about design

- Be clear about the use case.
- Consider the context the chatbot will be deployed.
- Involve typical end users in initial design.
- Identify the key therapeutic components.
- Work with content experts to identify tags.
- Sample transcripts need to have variability in quality.
  - Ensure the data pull has good population representation.
- Develop Robust safety protocols.

Trial design

- Superiority vs Non-inferiority
- Sample selection
- Control condition considerations
  - Placebo
  - Waiting list
  - Human delivery
  - Usual Care
- Follow up period

Important outcomes and processes to demonstrate in an efficacy RCT

- Safety
  - Number needed to harm.
  - Number or conversational errors/need for correction.
- Efficacy
  - Clinical effect under controlled circumstances.
- Fidelity/benchmark performance
  - Chatbot quality in delivering therapeutic content.
- Flexibility
  - Chatbot shows flexibility in delivery of content.
- Patient centeredness
  - Chatbot content feels empathic, uses patient context to explain principles.

Important outcomes and processes to demonstrate in an effectiveness RCT

- Population level Safety
  - Number needed to harm.
  - Number or conversational errors/need for correction.
  - Corrections for divergence from the conversational framework.
- Effectiveness
  - Clinical effect in different populations.
- Fidelity/benchmark performance
  - Chatbot quality in delivering therapeutic content; acceptable deviations in content.
- Flexibility
  - Chatbot shows flexibility in delivery of content, in different populations.
- Patient centeredness
  - Chatbot content feels empathic, uses patient context to explain principles, optimal engagement.

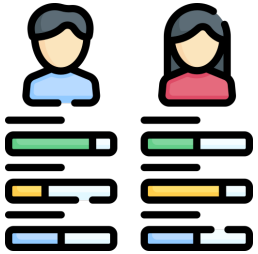
Post trial variations in communications, novel development

- Levels of AI constraint.
- On-going surveillance.
- Novel interactions? Back to testing.

Hybrid model for Efficacy trials: Efficacy-Effectiveness studies.

Does the intervention work/Safety?

Does it engage the target?



Any populations the intervention does not work for?

What clinical and system structures are needed to implement?

Thank you.

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