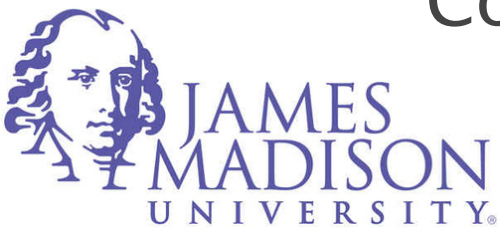
# Need for Adaptive Research Designs in Speech Language Pathology

Christy L. Ludlow, PhD
Communication Sciences and Disorders
Email :ludlowcx@jmu.edu



# Disclosures

- Receive research support and serve as a consultant to Passy Muir, Inc.
- Am an inventor on patents for devices for dysphagia
- Receive research support from National Institutes of Health
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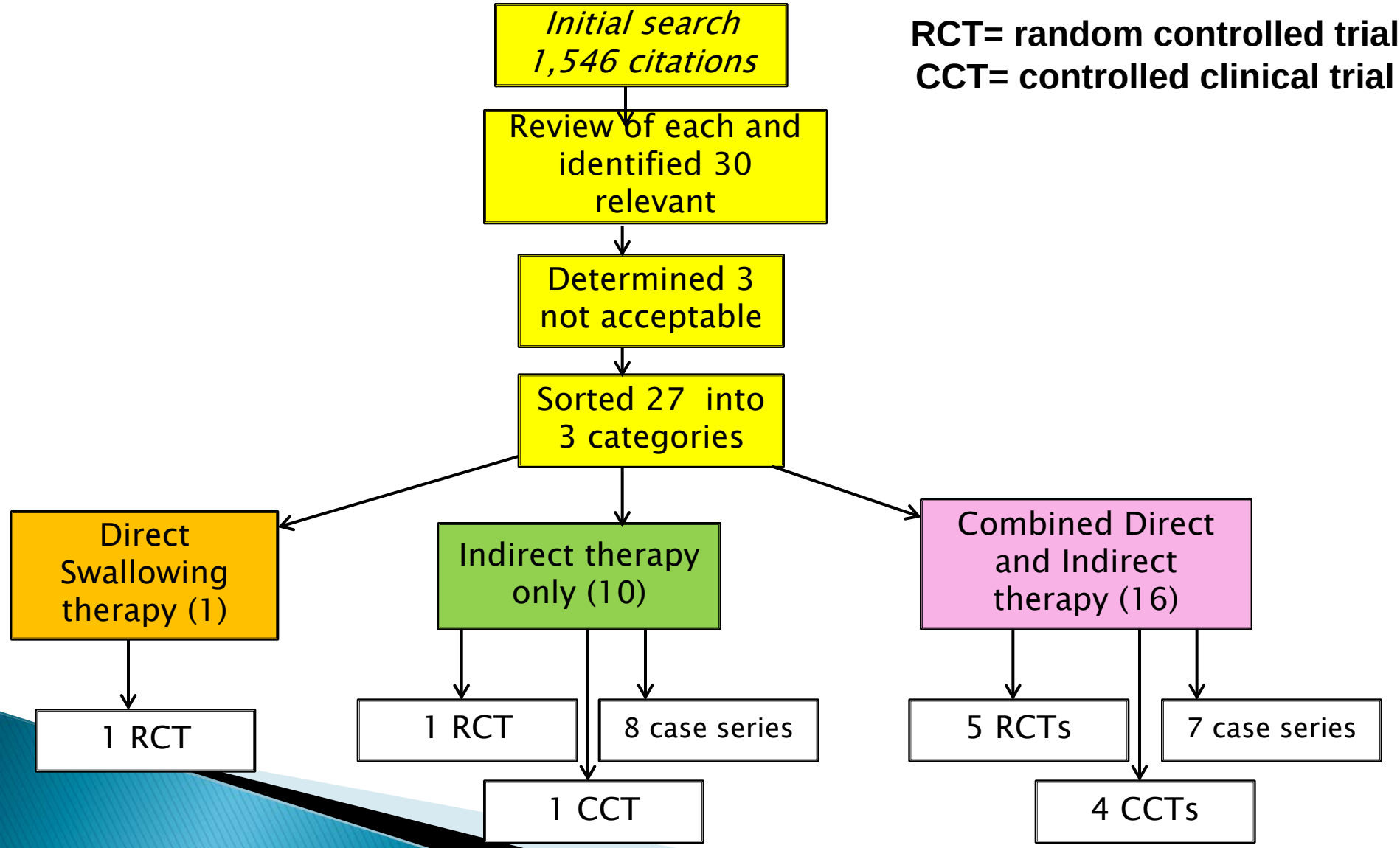
Drulia and Ludlow, "Relative Efficacy of Swallowing versus Non-swallowing Tasks in Dysphagia Rehabilitation: Current Evidence and Future Directions"

*Current Physical Medicine and Rehabilitation Reports*, ePub Sept. 2013

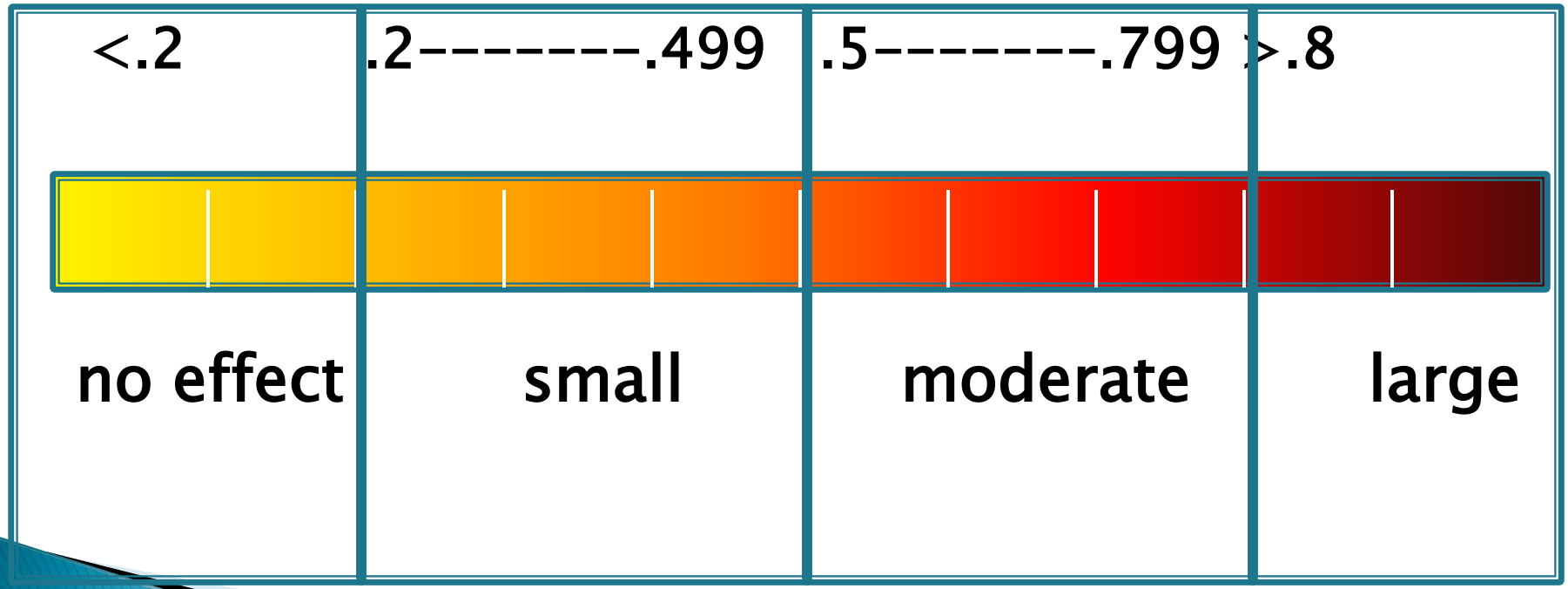
**RCT= random controlled trial**
**CCT= controlled clinical trial**



# Effect Sizes for Dysphagia Therapy

Computed Cohen's *d* for therapy effect

Effect size (*d*) = Change in mean/ S.D.



# Effect Sizes for Dysphagia Therapy alone

- Effect sizes are small for behavioral therapy alone (.3-.4) Mendolsohn during therapy

## Effect sizes for other modalities alone

- Other single modalities of therapy have higher effect sizes (.45-.8) e.g. rTMS (5Hz), Icing, exercise alone (jaw opening), DBS, Levodopa

# Effect sizes for Dysphagia Therapy Combined with Other Modalities

- Effects sizes range from .3 to 1.2,
  - Exercise plus swallowing therapy,
  - tDCS,
  - Videofeedback plus therapy
  - NMES plus swallowing therapy

- Spontaneous recovery alone has a 1.2 effect size during first 0-3 months

# Effect Sizes

- Swallowing Therapy alone ES= .4- .5 (Small)
- Other therapies (Deep Brain Stim, LevoDopa, Transcranial Magnetic Stim) alone
  ES= 0.4-.7 (Small to Moderate)
- Other therapies + Swallowing Therapy Combined
  ES= .6- 1.2 (Moderate to Large)

Spontaneous recovery alone post CVA
ES= 1.2 (Large)

## Current Therapy Regimens are infrequent and short

Usual Dosage for Inpatient Rehabilitation

- Dosage duration=2 weeks
- Intensity= 1 hour per weekday
- Total exposure 10 hours
- # swallows =600

Usual Dosage for Outpatient Rehabilitation

- Dosage =4-6 weeks
- Intensity= 1 hour per week
- Total exposure 6 hours
- # swallows= 360

# Methods for Optimizing Therapy

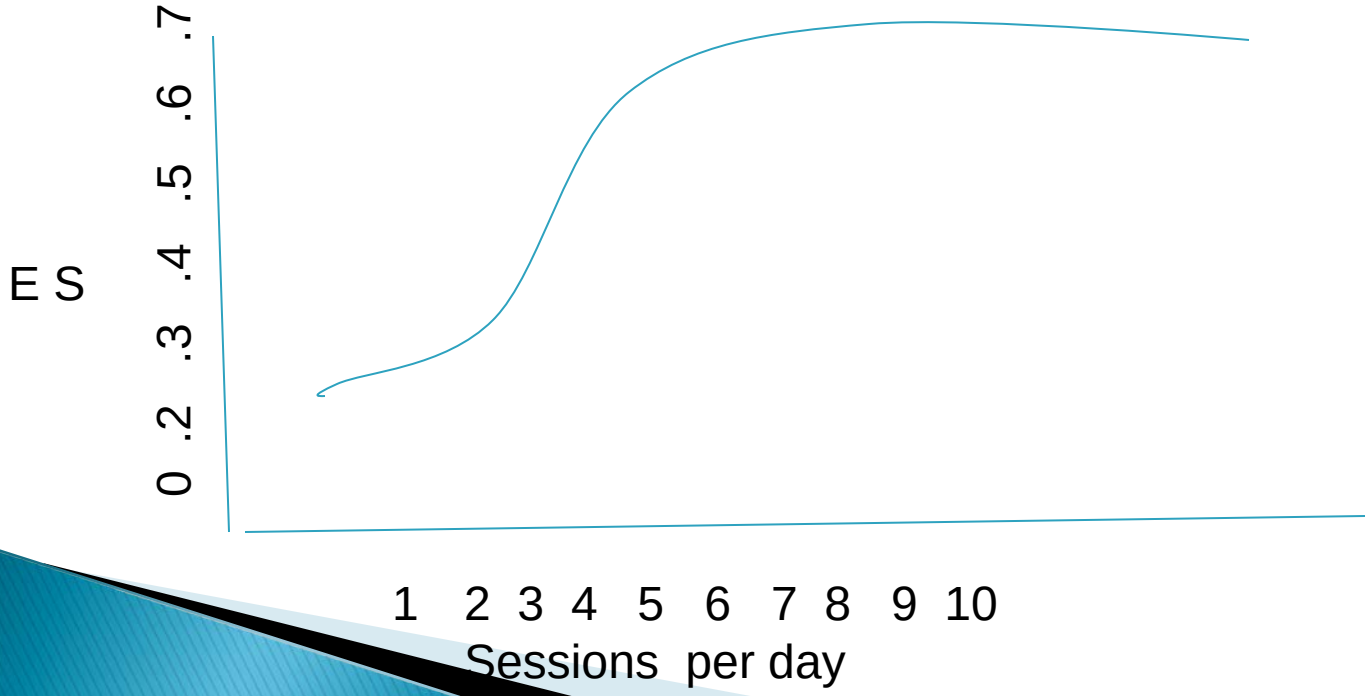
- Extending dosage by prolonging therapy program
- Increasing  intensity by using multiple therapy sessions a day
- Shortening session duration to avoid fatigue
- Combining other modalities such as cortical stimulation with therapy

# Adaptive Designs to Find the Most Effective Therapy Regimen

- Do adaptive studies before embarking on an RCT to determine optimal therapeutic program
  - Find most effective treatment intensity, # trials per day without patient fatigue
  - Find most effective session duration of treatment, shorter may be more effective
  - Find most effective treatment dosage, total # sessions

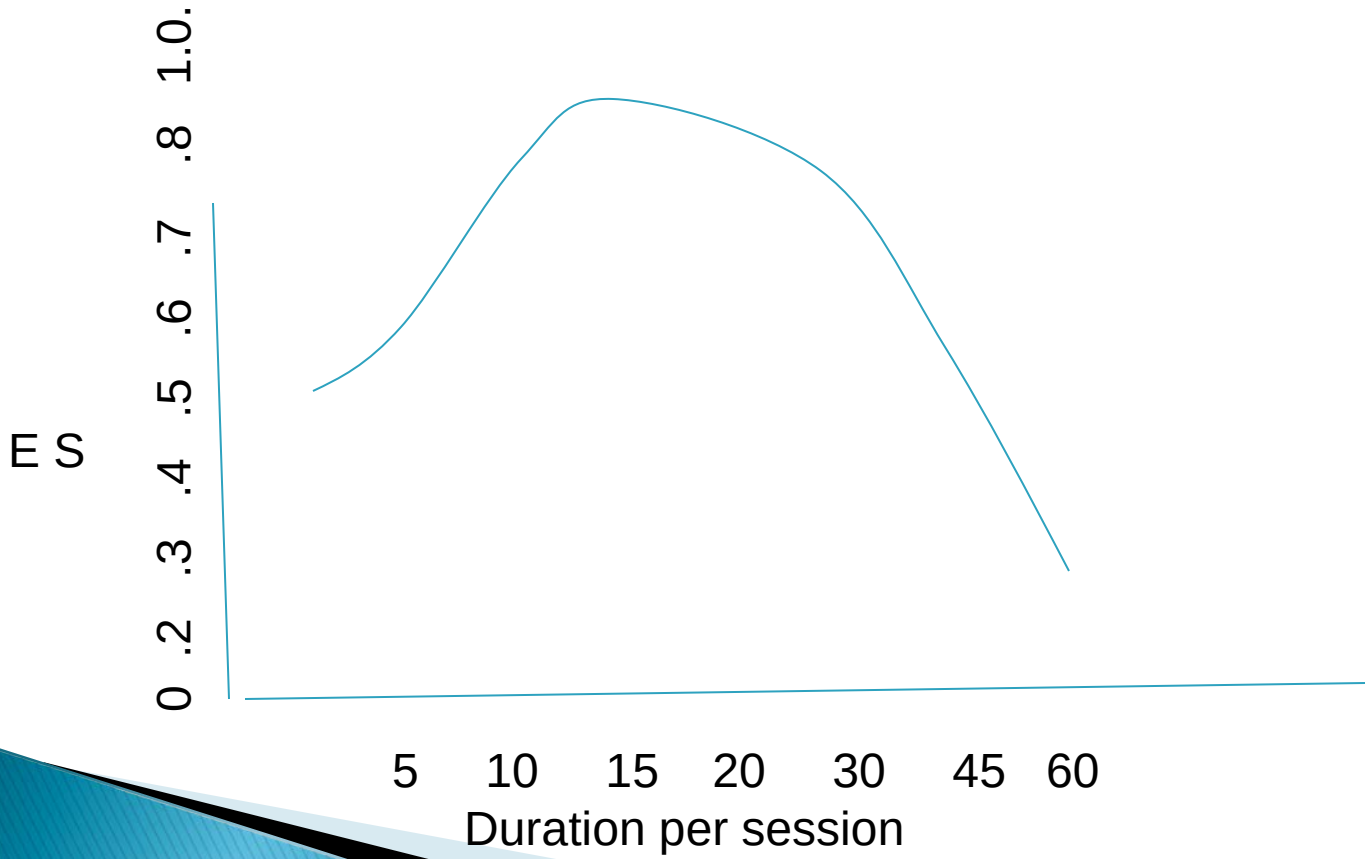
# Questions to ask of adaptive designs

- **Sessions per day,** 1 per day is usual
- If therapy was in patient's environment could have multiple sessions of short duration per day



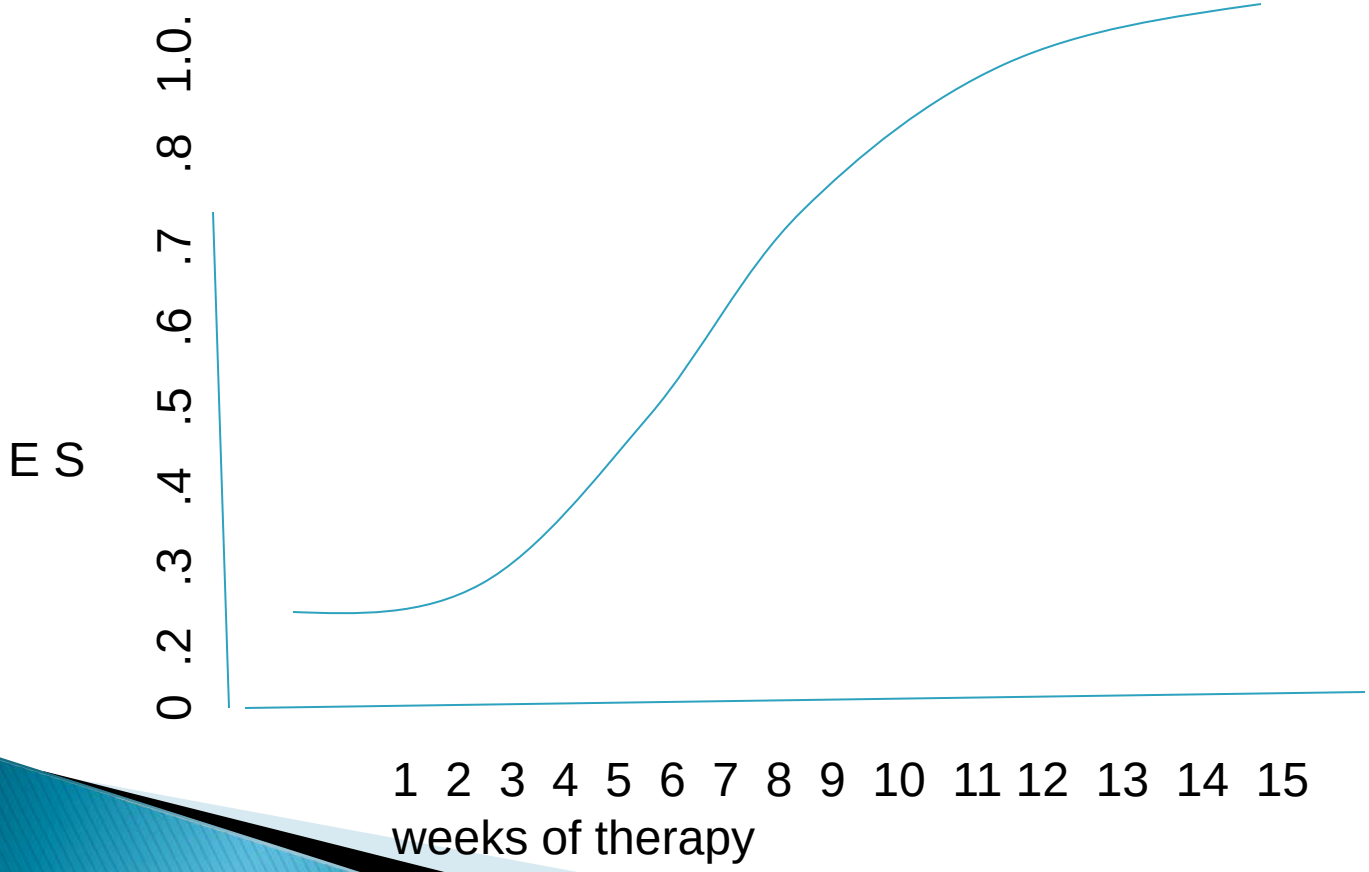
# Session Duration (minutes)

- 1 hour may not be optimal



# Therapy period

- 2 weeks may not be optimal



# When are Adaptive Designs useful?

- Conduct  BEFORE designing an RCT
- Adaptive designs are used to  identify optimal treatment regimen before doing a costly and lengthy RCT
- May need different regimens for different treatments for different types of patients
- Statistical analysis done independently by biostatistician and reported to DSMB