How should games as interventions be studied?: Lessons from clinical research

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Study design desidera

• Active comparison group
  – Matched on arousal level; duration; basic perceptual-motor requirements; practice time (objectively assessed); engagement

• Untreated control group

• Importance of random assignment

• Obtain data on game preference prior to random assignment

• Blind assessment (experimenters blind to game type)
The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR)

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ABSTRACT

Most of the extant literature investigating the health effects of mindfulness interventions relies on wait-list control comparisons. The current article specifies and validates an active control condition, the Health Enhancement Program (HEP), thus providing the foundation necessary for rigorous investigations of the relative efficacy of Mindfulness Based Stress Reduction (MBSR) and for testing mindfulness as an active ingredient. 63 participants were randomized to either MBSR (n = 31) or HEP (n = 32). Compared to HEP, MBSR led to reductions in thermal pain ratings in the mindfulness- but not the HEP-related instruction condition (η² = .18). There were significant improvements over time for general distress (η² = .09), anxiety (η² = .08), hostility (η² = .07), and medical symptoms (η² = .14), but no effects of intervention. Practice was not related to change. HEP is an active control condition for MBSR while remaining inert to mindfulness. These claims are supported by results from a pain task. Participant-reported outcomes (PROs) replicate previous improvements to well-being in MBSR, but indicate that MBSR is no more effective than a rigorous active control in improving these indices. These results emphasize the importance of using an active control condition like HEP in studies evaluating the effectiveness of MBSR.
Study design desidera, continued

• Length of training?
• Pre, post and follow-up measures
• Obtaining measures of game playing during follow-up period
• Statistical and data analytic issues
  – Reliability of measures
  – Intent-to-treat analyses
  – Baseline adjusted scores
• Beyond main effects and interactions
  – Importance of individual differences
Types of outcome measures

• Behavioral
  – RT
  – Accuracy
  – Eye tracking
  – Decision making
  – Observations of social and emotional behavior
  – IAT

• Brain
  – fMRI
  – EEG/ERP
  – Structural
  – DTI
Types of outcome measures, continued

- Peripheral measures
  - Salivary measures
    - Cortisol
    - Alpha amylase
  - Startle
  - Electrodermal
  - Facial EMG
  - Cardiovascular
  - Sleep