

# Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple, Clinic-based Interventions: a Randomized-Controlled Trial (NCT04772755)

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# Disclosure



Dr. Smith has disclosed the following financial relationships. Any real or apparent conflicts of interest related to the content of this presentation have been resolved.

Affiliation / Financial Interest	Organization
Research Support for Current Study	Centers for Diseases Control and Prevention
Research Contracts Paid to Institution for COVID clinical trials	Pfizer

# Unapproved or Off Label



## Disclosures for

Michael J. Smith MD, MSCE

**Presenter:** Dr. Smith has documented this presentation ***will not*** involve discussion of unapproved or off-label, experimental or investigational use.



# Background and Study Design



- There are no evidence-based recommendations for the prevention of post-vaccination syncope
- Randomized-controlled trial of adolescents receiving at least one IM vaccine
  - 1:1 randomization to usual care or a combined intervention consisting of Buzzy® (vibration and cool pack device, reduces injection site pain) and electronic game (active distraction)
- Primary objective: Assess the efficacy of the intervention to decrease presyncope, a surrogate for syncope
- Secondary objectives: pre- and post-vaccination anxiety, post-vaccination pain, acceptability

# Results



- 340 adolescents (10-14 years) enrolled
  - 332 included in the modified intention to treat group
- There was a 25% reduction in presyncope in the intervention group
  - 48% versus 36%, ( $p = 0.02$ )
- Pain at 1-3 minutes was also decreased in the intervention group
  - Mean Wong-Baker Faces Pain Score 3.3 vs 2.5 ( $p = 0.006$ )
  - Proportion with Pain Score  $> 4$ 
    - 46% versus 32% ( $p = 0.009$ )
- There was no difference in state anxiety between the two study groups

# Conclusions



- The combination of Buzzy® and distraction with video games decreased the risk of post-vaccination presyncope by 25%
- This efficacy was likely driven by decreases in pain 1-3 minutes post-vaccination
- The study interventions were well-accepted by participants