Virtual Reality and Gaming Technology in Clinical Research: Past Trends and Future Prospects

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Introduction

- Digital therapeutics (DTx) is a category of regulated software designed to improve health outcomes via the delivery of evidence-based behavioral or physical therapy to treat or prevent disease.
- Virtual reality (VR) and video games (VG) represent novel DTx modalities with the potential to increase patient engagement with DTx.
- Due the digital nature of DTx, studies of VR and VG may be well suited to decentralized (DCT) study methods.

Objective

- To characterize how VR and VG have been funded and studied using metadata from a large clinical trial registry.

Methods

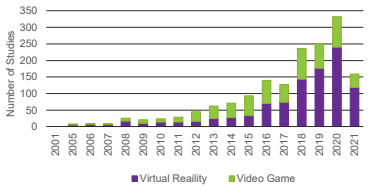
- The clinicaltrials.gov (CT.gov) database was searched for studies containing "(video game OR gaming OR game OR virtual reality AND NOT board OR ball)" registered up to and including 03-Jun-2021.
- The type of technology (VR or VG) under investigation was determined based on study title, the intervention(s) and the study outcome measures.
- 3,041 studies were returned of which 1,398 were excluded from the analysis primarily due to the inability to determine the type of technology being studied from the available search information.

Results

Trends over Time

- 1,643 studies were analyzed (VR=1,000 [60.1%], VG=643 [30.9%]) of which 67.3% were registered in the last 5 years (Fig.1).

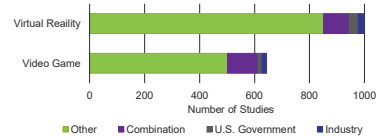
Figure 1. Studies Registered by Year



Funding Sources

- 82.3% of studies were exclusively funded by sources classified as "other", which includes universities, community-based organizations and individuals (Fig. 2).
- 3% of studies were funded solely by US government sources.
- Only 2.3% of studies were funded exclusively by industry.
- 12.4% of studies were supported by a combination of funding sources.

Figure 2. Study Funding Sources



Study Designs

- 94.1% of studies were interventional and the most common interventional model was the randomized, parallel groups design (60.1% [VR 61.1%], [VG 59.7%]) (Fig. 3 and Fig. 4).

Figure 3. Studies by Study Type

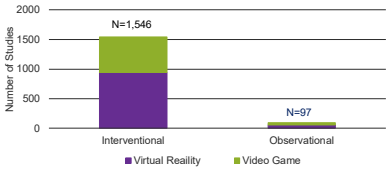
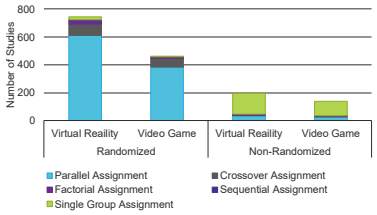


Figure 4. Interventional Study Designs



- The most common observational model was the prospective, cohort design (Fig. 5).
- Study sample size data was available for 1,626 studies, the median sample size across all studies was n=57 (Tab. 1).
- 71.4% had a sample size of n<100, which are classified by NIH as small studies [1].

Figure 5. Observational Study Designs

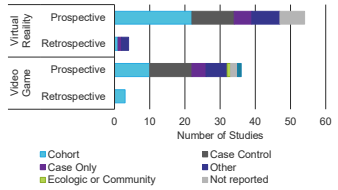


Table 1. Sample Size By Study Type

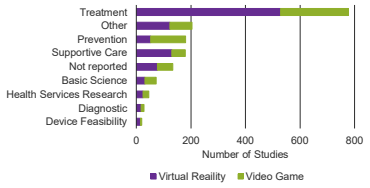
Sample Size	Number of Studies (%)	
	Interventional	Observational
<100	1096 (67.4)	65 (4.0)
100 to 999	405 (24.9)	25 (1.5)
≥1,000	30 (1.8)	5 (0.3)
Median (IQR)	57 (30 -100)	

IQR=Interquartile range

Primary Research Purpose

- Most studies investigated treatment effects (47.3% [VR 52.9%, VG 38.7%]) (Fig. 6). 11% of studies investigated preventative effects (VR 5.3%, VG 19.9%).

Figure 6. Study Purpose by Tech Type



Discussion

- The low percentage of industry-funded VR and VG studies contrasts data for interventional drug studies, 48% of which are funded by industry.[2]
- DTx could be considered well suited to virtual or DCT study approaches, and the ability to apply such approaches to study VR and VG presents an exciting opportunity to advance the development these technologies in real-world settings, which could enable larger, more robust trials.

Conclusions

- Most clinical research on VR and VG has been small interventional studies investigating treatment effects of these technologies.
- These findings point to a paucity of large, industry funded, studies of VR and VG technologies.
- DCT study approaches may facilitate the conduct of large robust studies in real-world settings.

Limitations

- The analysis was limited to structured CT.gov metadata and the addition of further data sources would provide a more comprehensive and robust analysis. The authors did not examine the accuracy of the CT.gov metadata used in the analysis.

References

1. Institute of Medicine (US) Committee on Strategies for Small-Number-Participant Clinical Research Trials; Evans CH Jr., Ildstad ST (eds). Small Clinical Trials: Issues and Challenges. Washington (DC): National Academies Press (US); 2001. Available from: https://www.ncbi.nlm.nih.gov/books/NBK223339/

2. Gresham, G., Meinert, J., Gresham, A. and Meinert, C., 2020. Assessment of Trends in the Design, Accrual, and Completion of Trials Registered in ClinicalTrials.gov by Sponsor Type, 2000-2019. JAMA Network Open, 3(8), p.e2014682. Available from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769830

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