Growth & Quality of Evidence for Evaluating Digital Health Interventions:
An Assessment of Registered Clinical Trials

Fujian Song

Norwich Medical School

University of East Anglia

Norwich, U.K.

Background & Aims

- The use of innovative digital health interventions (DHIs) has been rapidly increasing in healthcare practice, and research evidence on the effectiveness of DHIs is urgently required.
- Aims: To assess the quantity, design quality and characteristics of DHI trials registered on ClinicalTrials.gov.

Methods

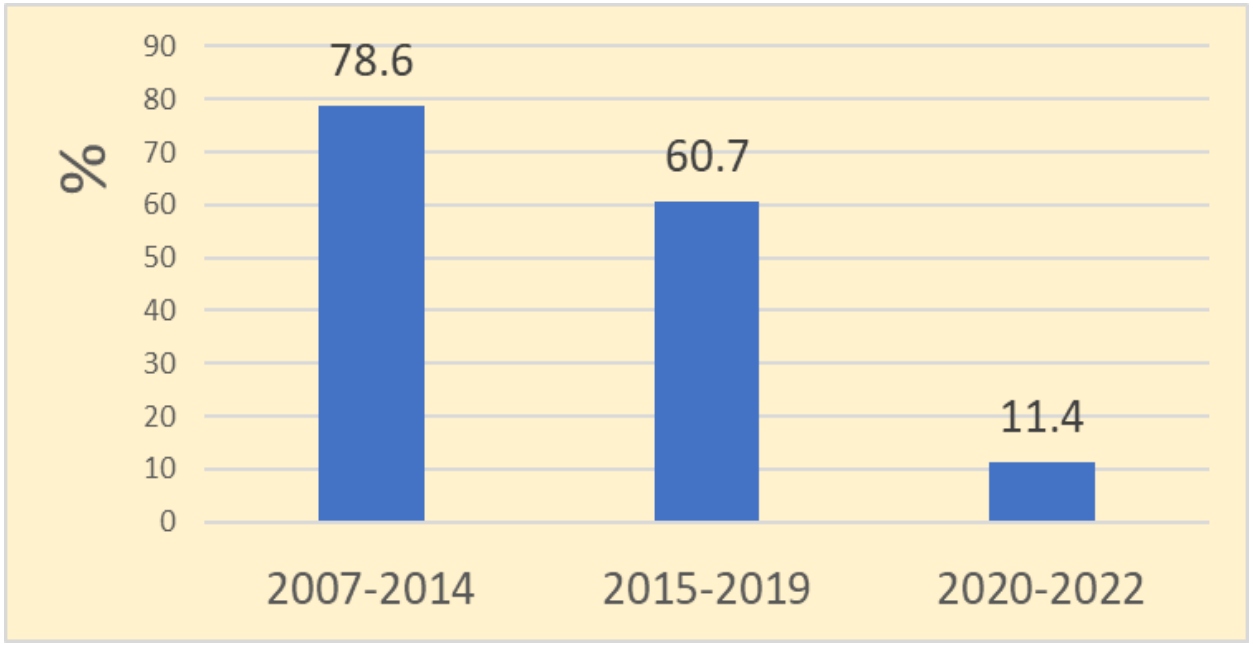
- We searched ClinicalTrials.gov to identify interventional trials on DHIs. There were no restrictions regarding DHI types and conditions.
- The assessment focused on changes in quantity and quality over time during 2007-2022.
- Annual growth rate: $exp(ln(n_t/n_0) /t) -1$

  where n_0 and n_t are the number of registered trial at time 0 and t.

Result-1: The annual growth rate

- A total of 860 registered DHI trials was included.

Year	No. of DHI trials	No. of increased
2007	1	--
2014	58	57
2019	622	564
2022	854	232



Result-2: Main characteristics of registered DHI clinical trials

- Majority of the trials were completed (75.3%), conducted in the USA (73.4%) and non-industry founded (83.1%).
- The purposes of most trials were categorised as treatment (35.8%), followed by health services research (16.0%), prevention (16.0%), and supportive care (14.2%).
- The major conditions concerned mental or behavioural disorders (25.7%), endocrine, nutritional or metabolic diseases (13.3%), certain infectious or parasitic diseases (9.9%), circulatory diseases (9.7%), and neoplasms (7.4%). It is particularly noticeable that the proportion of DHI trials of infectious diseases increased from 7.6% before 2020 to 16.0% since 2020.

Result-3: Quality of registered DHI trials

Proportion by trial design

	2007-2014	2015-2019	2020-2022
RCTs	89.7%	74.5%	77.7%
Double-blinded	12.1%	14.4%	18.5%
Phase ¾	12.1%	5.9%	5.5%
Planned/actual sample size>200	49.1%	32.6%	37.3%

Limitations

- This study included clinical trials registered on one clinical trial registry, and did not include relevant trials from other clinical trial registries.
- We did not evaluate results of the completed studies
- Information provided in trial registers is usually more limited than fully published studies.

Conclusions

- The recent growth of the quantify of registered DHI trials has become slower than before, except of trials of infectious diseases.
- There has been no improvement in the design quality of registered DHI trials in terms of sample size, randomised allocation, and masking.
- Further investigation is required to understand the impact of COVID-19 Pandemic on the evidence evolution for the use and evaluation of digital health interventions.

Main references

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- Masanneck L, Gieseler P, Gordon WJ, et al. Evidence from ClinicalTrials.gov on the growth of Digital Health Technologies in neurology trials. NPJ Digit Med 2023;6(1):23. doi: 10.1038/s41746-023-00767-1 [published Online First: 2023/02/11]