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

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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: $\exp\left( \ln\left( \frac{n_t}{n_0} \right) / t \right) - 1$

  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.

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of DHI trials</th>
<th>No. of increased</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>1</td>
<td>--</td>
</tr>
<tr>
<td>2014</td>
<td>58</td>
<td>57</td>
</tr>
<tr>
<td>2019</td>
<td>622</td>
<td>564</td>
</tr>
<tr>
<td>2022</td>
<td>854</td>
<td>232</td>
</tr>
</tbody>
</table>
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.
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<tbody>
<tr>
<td>RCTs</td>
<td>89.7%</td>
<td>74.5%</td>
<td>77.7%</td>
</tr>
<tr>
<td>Double-blinded</td>
<td>12.1%</td>
<td>14.4%</td>
<td>18.5%</td>
</tr>
<tr>
<td>Phase ¾</td>
<td>12.1%</td>
<td>5.9%</td>
<td>5.5%</td>
</tr>
<tr>
<td>Planned/actual sample size&gt;200</td>
<td>49.1%</td>
<td>32.6%</td>
<td>37.3%</td>
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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
