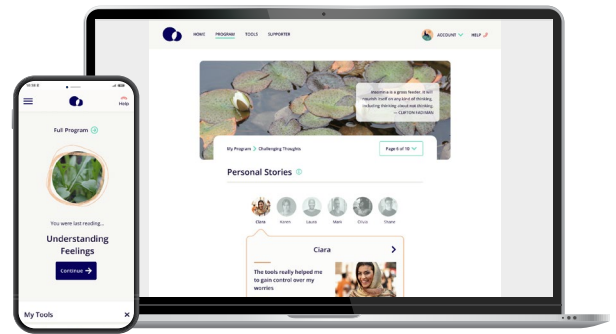




A commitment to scientific rigour and clinically proven outcomes will have a lasting effect on how digital behavioural health interventions are implemented and used to treat and improve the quality of life of people across the world.



Venture capital companies have been increasingly investing in digital mental health and wellness-oriented technology with a record-breaking \$5.1 billion in 2021.

Tech entrepreneurs are often encouraged to “fail fast, fail often,” regardless of risk, which can mean less time and resources towards validating the product.

This has led to Digital Mental Health Intervention (DMHI) companies making misleading claims about their evidence and clinical validation.

Claims made about DMHI are typically not bound by any regulation or proof which can result in false and misleading claims, exposing risks to vulnerable end-users in need of the mental health care.

We encourage stakeholders to empower themselves with an understanding of how to evaluate the reliability and validity of research and claims pertaining to DMHI.

Ask these five questions when reviewing the evidence and claims of digital mental health companies.

1 Is the product truly evidence based or merely “evidence-informed”?

A large number of DMHI on the market that claim to be “evidence-based” or “clinically proven” are actually only “evidence-informed.” This means the product is relying on evidence that other researchers or companies have generated instead of being directly evaluated in a well-designed research study. Because no two interventions are exactly the same, it is essential that each product conducts its own effectiveness research to ensure users are getting precisely what the product is claiming to provide.

2 What type of research trial was employed?

While expensive and time consuming, Randomised Controlled Trials (RCTs) remain the gold-standard for proving the effectiveness of clinical and medical interventions. Generally, evidence from RCTs should be required when a DMHI represents a novel intervention or is being delivered through a new digital medium. However, RCTs can be expensive and time-consuming, and in some instances, well-designed single-arm trials might be considered appropriate for validating a new digital CBT product. This is especially true where a DMHI is based on a previously validated digitised mental health treatment.

3 Were the trial participants appropriately representative?

Many kinds of biases can emerge when selecting participants for intervention studies, which can affect the validity and real-world relevance of research findings. Samples are best acquired by randomly selecting a large sample of participants from the target population.

4 Has the research been published in a peer-reviewed journal?

DMHI companies often self-publish articles to avoid the formal rigorous evaluation that is required for publication in peer-reviewed journals. It is key to ensure that a company demonstrates a history of, and continuous commitment to, publishing their research evidence in reputable peer-reviewed journals.

5 Has there been an appropriate level of transparency about how outcome variables are defined?

Outcomes such as ‘improvement’, ‘reduction’ and ‘engagement’ are often used without explanation. Inconsistent criteria to measure outcomes makes interpretation and comparison of results very challenging. It is important to understand the definitions of outcome measures and determine whether they have real-world relevance.

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