

Patient safety outcomes and unintended consequences of digital mental health interventions: PPI to inform a systematic review

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Introduction

Digital mental health interventions (DMHIs) can be accessible online via various technologies such as websites, apps, and chatbots, and aim to provide support to people experiencing mental health challenges. <sup>(1)</sup>

Advantages:

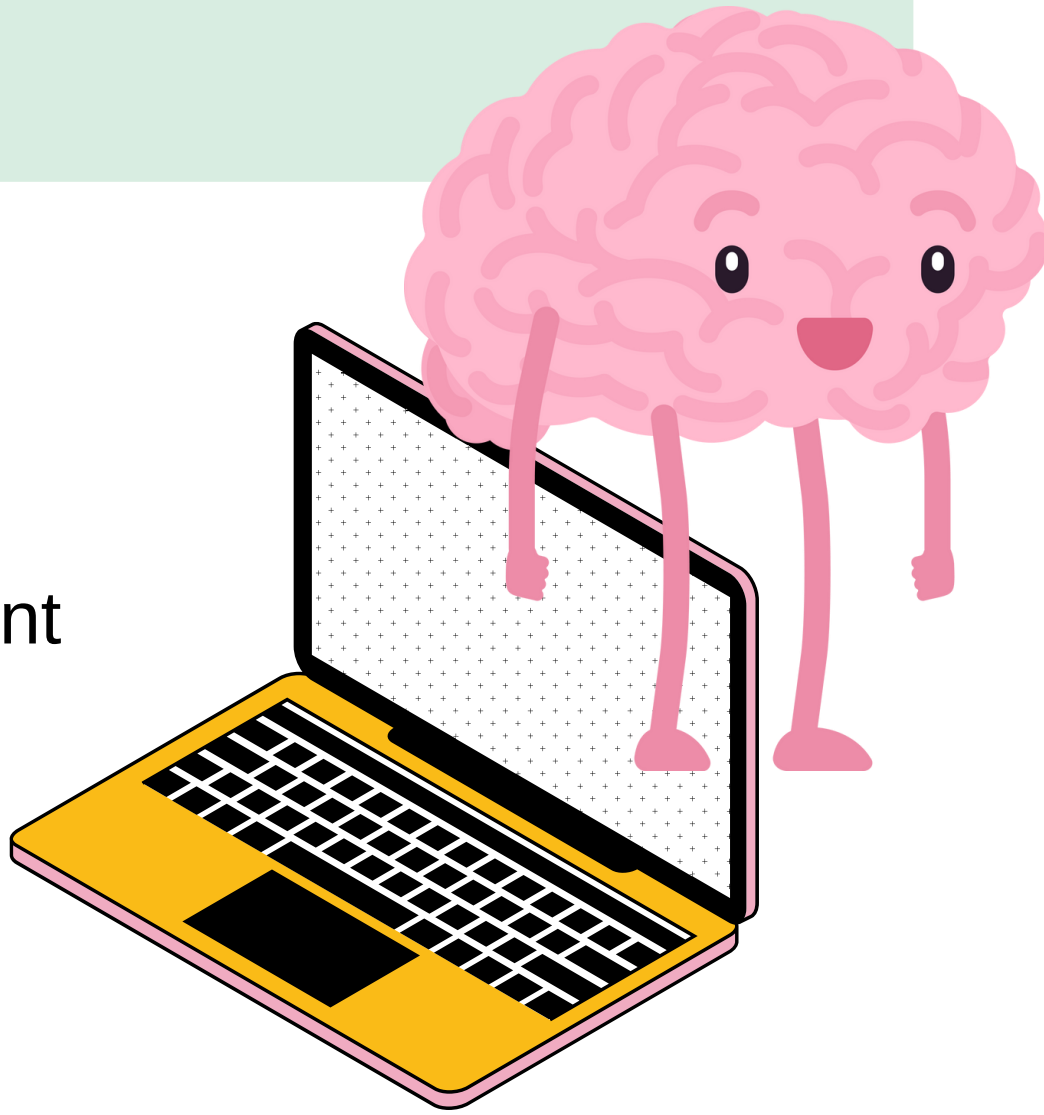
- Convenient way to access support in a private and safe space
- Scalable
- Can be implemented cheaply
- Can be more accessible than face-to-face interventions <sup>(2)</sup>

However, understanding the unintended consequences and safety risks to people when using DMHIs needs further investigation.

Unintended consequences are any unexpected event that occurred during the research that was noticeable or observable, and assumed to be related to the intervention used in the study. <sup>(3)</sup>

Aim

We aim to systematically review the literature reporting clinical trials of DMHIs that highlight patient safety related incidents and unintended consequences of the interventions.



Research question

The public contributors provided feedback on the research questions and highlighted that it is important to use the term ‘people’ instead of ‘patients’ because not everyone accessing digital mental health interventions will be a patient. The word ‘applied’ was also changed to ‘used’ based off the feedback from the public contributors.

Following the PPI workshop, the research questions were updated to:

1

What are the unintended consequences of digital mental health interventions used to prevent depression and/or anxiety in people?

2

What are the unintended consequences of digital mental health interventions used to treat depression and/or anxiety in people?

“People” not “Patients”

Methods

PsycINFO, EMBASE, MEDLINE, and Web of Science will be searched, and studies published in the last 20 years will be retrieved.

Search terms relate to the population, intervention, and study design under investigation. For example, “mental health”, “depression”, “anxiety”, “digital intervention”, and “RCT”.

Inclusion criteria

The study includes a DMHI for depression and/or anxiety

The study design is a randomised controlled trial (RCT)

The study is published in English

The study reported on the risks, safety, harm, negative effects, or unintended consequences of the DMHI

Exclusion criteria

The study design is not a RCT

The intervention in the RCT is not focused on depression or anxiety

The intervention is not digital

The study is not published in English

No comparison group included in the study

Participants in the RCT are exclusively caregivers/families of people with anxiety and/or depression

Patient and Public Involvement (PPI)

An online workshop was conducted with 3 people (aged 18+) with lived experience of anxiety and or/depression, and experience of using digital mental health interventions.

At the workshop, the public contributors shared their views to contribute to the development of the systematic review.

The 3 public contributors:

- Shared their lived experience to help identify what the unintended consequences of digital mental health interventions could be
- Helped clarify the research question for the systematic review
- Helped determine the definitions that will be used in the systematic review
- Helped to identify search terms that need to be included in the systematic review

PPI workshop insights

Next steps and implications

• Conduct the formal searches of the databases and consult with the second reviewer

• Conduct a PPI workshop with the public contributors to synthesise the results

• Write up the results

This research can inform the safe implementation of interventions in the future by focusing on increasing patient safety and reducing unintended consequences that can arise during implementation.

This research can also inform the development of future digital mental health interventions, by highlighting unintended consequences that need to be mitigated against, and patient safety areas that need to be improved on.

Impact following PPI

The definition of ‘unintended consequences’ was updated for this systematic review following the PPI workshop. Initially, the review was going to focus on identifying unintended consequences such as novel symptoms, increases in symptoms that the intervention was aiming to reduce, and increased rumination. Now the definition of unintended consequences will be broader, to also include other unintended consequences of using DMHIs, such as increased digital time.

References

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