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How is engagement reported in digital mental health interventions?

Results of Systematic Review

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Introduction

Digital Mental Health Interventions (DMHI) offer a scalable solution to an increasing number of patients with mental health conditions. However, when evaluating how well DHMIs work in randomised controlled trials measuring and adjusting for user engagement is critical.

To find out whether this is currently being done we undertook a systematic review to assess clinical trial publications of DMHI over the last 5 years (2016 – 2021).

Methods

Databases Searched:
MEDLINE, PsychINFO, CENTRAL, Embase

Search was completed in September 2021 across 4 databases, the inclusion criteria for studies were:

- **Intervention** - An app or website where participants drive the frequency and timing of access
- **Participants Diagnosis** – Clinical or self-referred diagnosis from the Cochrane list of Common Mental Disorders.
- **Study Design** – The study must be a randomised controlled trial to assess clinical efficacy.

Definitions:

Indicator – a collected app/web parameter that allows identification of a user's engagement level (e.g. pageviews)
User Engagement – how individuals have accessed and interacted with the intervention during the study
Active User – a pre-specified engagement criteria where the intervention is expected to provide benefit.

Outcomes:

1. **Trial and Participant Characteristics**: how are these studies designed?
2. **Engagement**: what indicators are used? How is engagement recommended, encouraged and reported?
3. **Statistical Methods**: how is user engagement adjusted for in trial analysis?

Results

184 studies were included in the review

Trial Characteristics:

- 119 (66%) studies recruited participants remotely
- 169 (91%) studies used a parallel design
- 145 (78%) studies had two arms
- The intervention period was on average 72 days (SD 51)

Participant Characteristics

- 132 (72%) studies did not report any participant ethnicity
- The mean age of participants was 34.1 (SD 11.1)
- 109 (60%) studies recruited participants with a confirmed clinical diagnosis
- Depression was the most common mental health disorder studied (41 studies, 22%)

Quality

- 36 (20%) studies did not report a protocol or trial number
- 43 (24%) studies did not report a planned sample size
- 94 (51%) did not recruit to their target sample size

Engagement Indicators (e.g. pageviews)

- 138 (75%) studies reported at least one indicator, the most common was "Modules Completed" (n = 78 studies, 43%)
- 41 (30%) studies only reported one indicator
- Studies reported a mean 2.6 (SD 1.5) indicators
- 38 (21%) studies reported an active user definition of what level of engagement was expected to provide benefit.

Analysis

- 34 (19%) studies performed an engagement adjusted analysis
- 29 (16%) studies used a per-protocol approach

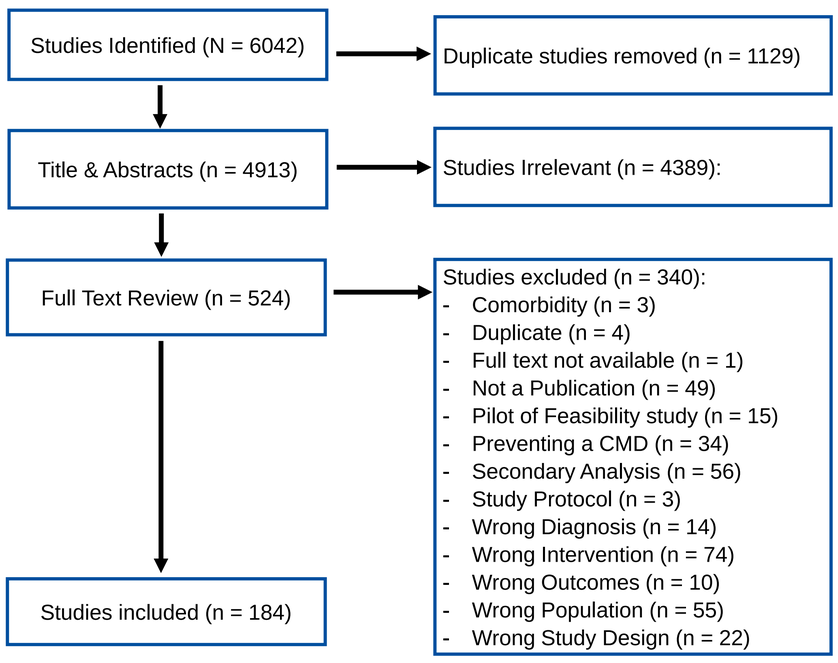

Figure 1 – *Prisma flowchart of studies screening and inclusion*

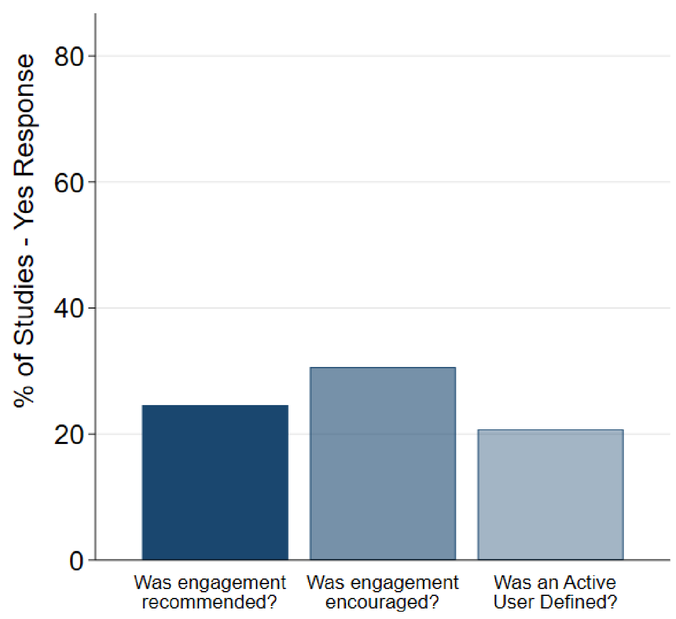

Figure 2 – *Proportion of studies identified as having described ways to promote user engagement in methods section.*

- ***Recommended*** *– defined as the participant was told how to use the intervention*
- ***Encouraged*** *– defined as when reminders (e.g. notifications or emails) are sent to the participant*
- ***Active User*** *– where a participants engagement meets a pre-specified criteria such that it is expected to provide benefit at this engagement level*

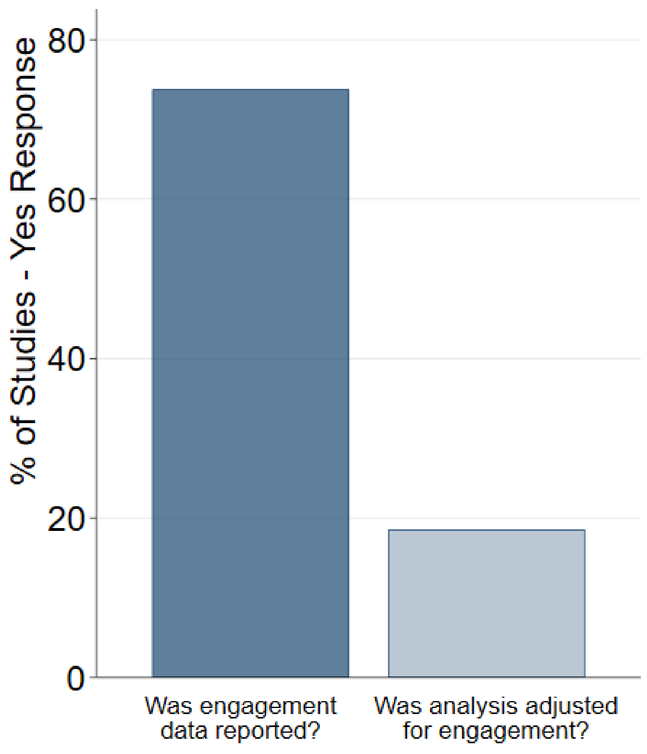

Figure 3 – *Proportion of studies identified as having reported in the results any engagement data descriptively or engagement considered in an analysis.*

- ***Reported –*** *the paper results describe activity for at least one indicator*
- ***Analysis –*** *the paper results report an intervention effect where user engagement has been considered*

Table 1 – *Description of the types of interventions included*

Intervention Description	N %
Delivery Method, n (%)	
App	33(18.0)
Website/Online	145(79.2)
Other	5(2.7)
Intervention Origin, n (%)	
Adapted	75(40.5)
Original	84(45.4)
Unclear	26(14.1)
Control Comparator Type, n (%)	
Alternative DMH Intervention	13(7.1)
Attention Control (fake version of DMHI)	30(16.4)
In-person Equivalent	10(5.5)
Placebo	5(2.7)
Standard of Care / Treatment as Usual	51(27.9)
Wait-list	74(40.4)

Table 2 – *Summary of types of indicators and where they're reported*

- *Duration examples = pageviews, length of session*
- *Frequency examples = logins, activated, comments posted*
- *Milestone examples = module completed, session completed*
- *Other examples = clinical feedback, non-participant activity, emails*

Indicator Type	Total Studies	Used in Recommendation			Used in Active User Definition		
		No	Yes	N/A	No	Yes	N/A
Duration of Use	67	8	11	48	12	6	49
Frequency of Use	147	24	5	118	31	9	107
Milestone Achieved	122	13	23	86	4	24	94
Other Indicator	22	6		16	7		15
Not Reported	47						

Discussion

Trial Characteristics & Quality

- Most studies used a traditional two arm parallel design not taking advantage of available modern efficient designs.
- Over half (51%) failed to recruit to their target sample size, suggesting this population are difficult to recruit
- The average intervention period was 72 days showing DMHIs are typically designed for repeated long-term use.

Engagement Indicators & Analysis

- Most studies (75%) included some description of user engagement, reporting at least one indicator showing how these interventions already have the capability to capture how interventions are used.
- Only 38 (21%) studies reported an active user definition where they had considered what level of engagement was expected to provide benefit.
- Even though many studies captured user engagement, very few (19%) assessed the impact this has in the intervention efficacy analysis.
- The majority of studies (85%) that did perform an engagement analysis used a per-protocol approach
- This is sub-optimal because the benefits of randomisation are not preserved due to some randomised participants being excluded

Conclusion

In conclusion, this review show many trials evaluating DMHIs use traditional two arm parallel. Many studies fail to recruit enough participants to have the right power. Even though 75% of studies reported user engagement data, only 19% attempted to assess the impact of user engagement in the efficacy analysis, but most using a per-protocol approach which is known to be biased. Further analysis is underway to explore the impact of adjusting for engagement on trial results. Recommendations will be drawn from the review results to develop an approach to incorporate engagement into efficacy analysis.

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