Full title:

No evidence of increased gaming-related problems with long-term use of a video game therapeutic: Exploratory endpoint findings from a randomized controlled trial

Short title:

No increase in gaming-related problems with video game therapeutic use

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Abstract

Digital therapeutics for mental health often face low patient engagement, which limits their clinical impact. Interventions that deliver treatment using a video game medium may improve engagement and therapeutic efficacy, but the putative emergence of gaming-related problems remains a concern among clinical stakeholders. We examined whether long-term engagement with *Meliora*, a video game therapeutic for adult major depressive disorder, was associated with changes in gaming-related problems in a three-arm randomized controlled trial. The intention-to-treat cohort (n = 1,001) had a mean age of 33.4 years (SD 9.3) and 64% were female. The Gaming Addiction Scale (GAS-7) scores decreased from baseline (week 0) to post-intervention (week 12) in the Meliora arm ($p = 8.1\times10^{-4}$) and in the treatment-as-usual arm ($p = 6.0\times10^{-6}$), with no significant change observed in the Sham arm (p = 0.39). Changes in GAS-7 scores were not associated with intervention use hours (Meliora: p = 0.17; Sham: p = 0.28) or with experienced immersion (Meliora: p = 0.93; Sham: p = 0.19). Deterioration analysis found worsening rates from baseline to post-intervention low and comparable across study arms. Analyses in the per-protocol completer cohort (≥24 h use) corroborated these findings, indicating that even higher use did not lead to increases in gaming-related problems. These results provide evidence that long-term use of a video game therapeutic does not increase gaming-related problems when risks are properly mitigated, suggesting that video games may provide a safe medium for digital therapeutics.

Author summary

Many patients use digital therapeutics insufficiently or drop out early, which limits their effectiveness and applicability in healthcare. Video game therapeutics deliver the treatment using an interactive video game as a medium to improve both engagement and therapeutic efficacy. However, extended use of video game therapeutics could inadvertently increase gaming-related problems. We examined whether long-term use of *Meliora*, a video game therapeutic for adults living with depression, was associated with increased gaming-related problems. We found that using *Meliora* or a highly similar Sham device did not increase gaming-related problems. Changes in gaming-related problems were not associated with the amount of time participants used the interventions, suggesting that typical use patterns are safe. We also found no relationship between experienced immersion and changes in gaming-related problems, suggesting that subjective immersion is distinct from problematic gaming. This study provides the first clinical evidence that extended engagement with a video game therapeutic does not increase gaming-related problems. These findings suggest that video games can be a safe medium for digital therapeutics in healthcare.

Keywords: Digital therapeutics, Depression, Executive functions training, Gaming addiction, Mental health, Video games, Video game therapeutics, Serious games

Introduction

Digital mental health interventions (DMHIs) can expand treatment reach for mental disorders with effectiveness comparable to face-to-face psychotherapies (1,2). Based on DMHIs, several commercial digital therapeutics (DTx) have been developed (3,4). Yet, engagement has remained a major barrier: most patients use these products less than recommended, and completion rates in routine care settings are, on average, only 25% (5). Given that long-term engagement predicts outcomes (5–7), compelling interventions are required.

As a novel form of DTx, video game therapeutics use a video game medium to deliver therapeutic mechanisms of action (8–10). Video games are highly popular and appealing, with 61% of the U.S. population aged 5–90 playing video games at least one hour a week (11). Compared to conventional therapeutics, video game therapeutics can have greatly improved appeal and engagement. This can promote experienced immersion and long-term use, which are prerequisites for intervention efficacy (8,10). However, the video game medium also raises concerns about gaming-related problems as adverse effects for these interventions (12). To the best of our knowledge, no prior randomized trial has tested whether long-term exposure to a video game therapeutic increases gaming-related problems.

Here, we asked whether the long-term use of a video game therapeutic influences gaming-related problems as measured by the Gaming Addiction Scale (GAS-7) (13). This analysis was a pre-registered endpoint in a randomized controlled superiority trial of a video game therapeutic for adult major depressive disorder (MDD), which compared a video game

investigational device ("*Meliora*") with a highly similar comparator device ("Sham") and treatment-as-usual (TAU) (10). In the present study, we evaluated whether the GAS-7 scores changed within and between the three study arms from baseline to post-intervention. In addition, we examined whether intervention use hours, experienced immersion, and background covariates were associated with GAS-7 changes, and evaluated GAS-7 score deterioration.

Methods

This study investigated whether long-term use of a video game therapeutic for adult MDD was associated with increased symptoms of gaming-related problems. This pre-registered exploratory endpoint was conducted within a randomized, double-blinded, comparator-controlled trial in Finland (ClinicalTrials.gov NCT05426265, June 16, 2022) described elsewhere (10). The trial was approved by the Helsinki University Hospital (HUS) Regional Committee on Medical Research Ethics (HUS/3042/2021) and the Finnish Medicines Agency (FIMEA/2022/002976). All patients provided informed consent digitally.

Patients and interventions

A total of 1,001 patients with MDD were randomized into Meliora (n = 337), Sham (n = 347), or treatment-as-usual (TAU, n = 317) arms. Key inclusion criteria were age 18–65 years, meeting diagnostic criteria for MDD based on a remote structured interview using the Mini International Neuropsychiatric Interview (MINI) version 6.0.0 module A (14), and absence of addictions to gambling or gaming. If the patient was not excluded by other

criteria and indicated potential gambling- or gaming-related addiction, gambling-related addiction was assessed using the Problem Gambling Severity Index (PGSI), with exclusion defined as a total score of ≥ 8 (15), while gaming-related problems were assessed with the Gaming Addiction Scale (GAS-7) so that exclusion was defined as endorsement of four or more items at a frequency of "sometimes" or higher (13). Full inclusion and exclusion criteria, recruitment procedures, and intervention design are detailed elsewhere (10).

The active investigational device, *Meliora*, delivered adaptive executive functions training (EFT) in a single-player video game format without social interaction. Highly similar Sham comparator matched audiovisual and narrative features but with reduced EFT training load. Patients used both interventions at home on their personal computers as adjunct to TAU with recommended use of 48 hours over the 12-week intervention period. Both interventions were limited to a maximum of 90 minutes per day.

Measurement of gaming-related problems and immersion

Gaming-related problems were measured with the Finnish translation of the 7-item Game Addiction Scale (GAS-7) (13,16). GAS-7 was administered at baseline (week 0), weeks 4 and 8, post-intervention (week 12), and at follow-up (week 24). Immersion was measured with the Finnish translation of the Immersive Experiences Questionnaire (IEQ) (17), administered at weeks 4, 8, and 12.

Statistical analyses

Analyses followed the statistical framework of the main trial (10). Between-group differences in gaming-related problems were evaluated using robust linear mixed-effects models on GAS-7 change-from-baseline scores at weeks 4, 8, and 12, with fixed effects for time and study arm, adjusted for baseline GAS-7, age, gender, education, income, and life status, and with participant-level random intercepts. Holm–Bonferroni correction was applied to between-group contrasts. Missing data were handled using the same multiple imputation procedure as in the primary trial analyses.

Associations between GAS-7 change from baseline to week 12 and total intervention use hours or experienced immersion were examined using robust linear regression adjusted for baseline GAS-7 and demographic covariates; these analyses were prespecified exploratory endpoints.

Additional supportive analyses included within-group change (week 0–12 and week 12–24; repeated-samples t-tests), covariate effects on GAS-7 change, and individual-level deterioration defined as ≥25% and ≥50% relative increases from baseline. False discovery rate correction was applied to supportive analyses. Per-protocol analyses included participants completing week 8 or 12 assessments with ≥24 h cumulative use.

Results

All enrolled 1,001 participants were included into an intention-to-treat (ITT) cohort (Meliora: $n = 337$; Sham: $n = 347$; TAU: $n = 317$). The mean age was 33.4 years (SD 9.3), and 64% were female. Baseline GAS-7 scores did not differ between groups (Meliora:

mean 11.66, SD 3.46; Sham: 11.54, SD 3.62; TAU: 11.62, SD 3.52; $p = 0.90$). As reported earlier (10), we observed no differences between Meliora and Sham in terms of average total intervention use time (18.4 h, SD 21.6; 18.2 h, SD 21.2, respectively, $p = 0.94$), or experienced immersion (118.9, SD 27.1; 115.9, SD 27.0; $p = 0.25$).

Within-group comparisons

Between baseline (week 0) and post-intervention (week 12) measurements, GAS-7 scores decreased with Meliora ($p = 0.003$, FDR-corrected) and TAU ($p = 0.003$, FDR-corrected), while we observed no change in Sham ($p = 0.333$, FDR-corrected) (Fig. 1, Table 1). GAS-7 scores remained stable from post-intervention to follow-up (week 24) measurements (Meliora: $p = 0.10$; Sham: $p = 0.16$; TAU: $p = 0.58$, FDR-corrected) (Table 1).

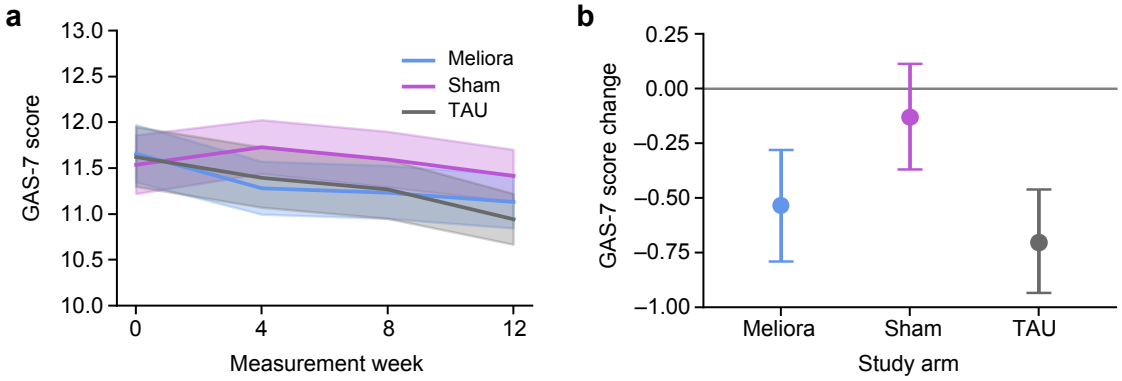

Fig 1: Gaming Addiction Scale (GAS-7) scores from baseline (week 0) to post-intervention (week 12) in the intention-to-treat (ITT) cohort. **a.** Mean GAS-7 scores over the 12-week intervention period across the three study arms. **b.** Change in GAS-7 scores from baseline to post-intervention. Shaded areas and error bars represent 5th–95th bootstrapped confidence intervals.

Table 1. GAS-7 scores (mean, 95% CI) for intention-to-treat (ITT) and per-protocol (PP) cohorts collected baseline (week 0), post-intervention (week 12), and follow-up (week 24).

Cohort	Arm	Baseline (week 0)	Post-intervention (week 12)	Follow-up (week 24)
Intention-to-treat (ITT)	Meliora (n = 337)	11.66 (11.29, 12.03)	11.15 (10.82, 11.48)	10.86 (10.56, 11.16)
	Sham (n = 347)	11.54 (11.16, 11.93)	11.43 (11.10, 11.78)	11.19 (10.88, 11.52)
	TAU (n = 317)	11.62 (11.24, 12.02)	11.11 (10.78, 11.46)	11.24 (10.91, 11.57)
Per-protocol (PP)	Meliora (n = 99)	10.48 (10.88, 12.12)	10.76 (10.25, 11.29)	10.66 (10.11, 11.23)
	Sham (n = 96)	11.53 (10.84, 12.24)	11.28 (10.64, 11.99)	11.12 (10.48, 11.80)
	TAU (n = 288)	11.59 (11.19, 12.00)	10.88 (10.54, 11.24)	11.09 (10.75, 11.44)

Between-group comparisons

Using robust linear mixed modelling, adjusted for baseline GAS-7 score and demographic variables, we found that Meliora reduced GAS-7 more than Sham (adjusted mean difference = –0.27, 95% CI [–0.38, –0.16]; d = –0.19; $p = 6.0\times10^{-6}$, two-sided, multiple comparisons corrected with Holm-Bonferroni). TAU also reduced GAS-7 more than Sham (–0.26, 95% CI [–0.37, –0.15]; d = –0.18; $p = 1.2\times10^{-5}$). No difference was observed between Meliora and TAU (p = 0.89) in GAS-7 score changes.

Covariate analysis

Female gender was associated with greater reduction in GAS-7 scores compared with males (adjusted mean difference –0.13, 95% CI [–0.24, –0.02]; d = –0.09; FDR-adjusted p

= 0.027). However, the effect size was small. Higher baseline PHQ-9 was associated with greater GAS-7 score reduction (–0.01, 95% CI [–0.02, –0.00]; d = –0.01; FDR-adjusted p = 0.027), but the effect size was negligible. Older age was associated with greater GAS-7 score increases (0.11, 95% CI [0.05, 0.16]; d = 0.08; FDR-adjusted p = $2.2\times10^{-}4$), whereas higher income was associated with greater reductions in GAS-7 scores (–0.13, 95% CI [–0.19, –0.06]; d = –0.09; FDR-adjusted p = $2.2\times10^{-}4$), but the effect sizes were small. No significant associations were found for education or life status.

Use hours and immersion

Using robust regression analysis, adjusted for baseline GAS-7 score and demographic variables, we did not find significant associations between baseline and post-intervention changes in GAS-7 and intervention use hours (Meliora: p = 0.15; Sham: p = 0.46). Similarly, we found no association between GAS-7 score changes and experienced immersion as measured by the Immersive Experiences Questionnaire (17) (Meliora: p = 0.45; Sham: p = 0.35).

Deterioration analysis

In a deterioration analysis, at the ≥25% threshold, 10.7% of participants in Meliora, 12.7% in Sham, and 11.4% in TAU arms met criteria for worsening from baseline to post-intervention; no between-arm differences were observed (pairwise Fisher's exact tests, Holm-corrected p-values = 1.00). At the ≥50% threshold, worsening rates were 3.0% in Meliora, 3.5% in Sham, and 4.4% in TAU arms, with no significant differences between groups (all Holm-corrected p-values = 1.00).

Per protocol analyses

Finally, we performed each of these analyses with the per-protocol completer cohort, which comprised patients meeting an adherence criterion of ≥24 h use (average total use times were 45.5h for Meliora, and 44.9h for Sham) (S1 Supporting information). These results corroborated those obtained with the ITT cohort, showing that even considerably greater average use times did not lead to gaming-related problems.

Discussion

Treatment dependency is a recognized concern in face-to-face treatments (18), but such problems have not typically been considered for DMHIs either with or without gaming elements (19,20). On the other hand, video games have been linked to gaming-related problems (21), which raises safety concerns for video game therapeutics. Here, the ITT within-group comparisons found that video game therapeutic use was associated with decreases in gaming-related problems measured with GAS-7, while no score changes were observed in patients using a highly similar Sham device. The deterioration analysis found that the individual-level worsening rates between baseline and post-intervention were low and comparable across the three study arms. These results were corroborated in the per-protocol completer analysis, which indicated that even greater average use times were not associated with increases in gaming-related problems. This study thus demonstrates that long-term use of an immersive video game therapeutic was not associated with an increase in gaming-related problems.

Excessive entertainment gaming has been linked to gaming-related problems (22). Here, we found no association between use hours and GAS-7 score changes, suggesting that moderate use times are safe for video game therapeutics. Importantly, these findings were obtained in a population without baseline gaming addiction and with interventions that incorporated device-level safeguards mitigating risks by restricting excessive daily use and excluding within-intervention social interaction. Changes in entertainment gaming during the intervention period were not evaluated, and it remains unclear whether the intervention use occurred in addition to or instead of entertainment gaming. Motivational and immersive aspects of gaming have also been associated with gaming-related problems (23,24). In an earlier study of the present data, we found experienced immersion to be a key driver for therapeutic efficacy (10). However, here we found no association between experienced immersion and gaming-related problems, indicating that immersive gaming in a therapeutic context is distinct from problematic use.

Previously, we assessed the safety of Meliora and Sham interventions using comprehensive open-ended self-report data on adverse events acquired with a novel multi-channel approach (25). An inductive analysis of these qualitative data revealed no reports of gaming-related problems (10), suggesting either an absence of subjectively experienced gaming-related problems, or unawareness of or underreporting of them. The present study resolves this central uncertainty with symptom measurements using a standardized scale.

In conclusion, these findings provide evidence that long-term use of a video game therapeutic does not increase the symptoms of gaming-related problems, showing that the

video game medium can be safely leveraged in digital therapeutics, provided that potential risks are appropriately mitigated.

Statements

Data availability

Pseudonymized individual participant data underlying the results reported in this article will be considered for sharing upon reasonable request to the corresponding author following publication. Data sharing is subject to approval by the Helsinki University Hospital Regional Committee on Medical Research Ethics, compliance with the General Data Protection Regulation (GDPR) and other applicable laws, and execution of a data use agreement. Requests must include a scientifically and methodologically sound research proposal outlining the intended use of the data.

Code availability

The statistical analysis code used to generate the results reported in this article will be made available upon reasonable request to the corresponding author following publication.

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Authors' contributions

The contributions are listed using the CRediT statement.

LL: Conceptualization, methodology, investigation, writing – original draft, writing – review and editing, project administration.

JJJ: Formal analysis, conceptualization, methodology, software, data curation, writing – review and editing, visualization.

SP: Writing – review and editing.

EI: Writing – review and editing.

JMP: Conceptualization, funding acquisition, supervision, writing – review and editing.

Competing interests

J.M.P., J.J.J., and L.L. are shareholders in Soihtu DTx Ltd, which develops digital therapeutics for major depressive disorder and holds intellectual property transferred from Aalto University with J.M.P., J.J.J., L.L. as co-inventors. J.M.P. is a part-time and J.J.J., L.L. are active employees at Soihtu DTx. L.L. is a member of the Board of Directors of Soihtu DTx Ltd. Soihtu DTx Ltd. did not play a role in the design, conduct, data analysis, or funding of the study.

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