Trials

STUDY PROTOCOL

Open Access

# The impact of gaming on functioning among people with schizophrenia: study protocol for a randomised controlled trial (GAME-A)

Maritta Välimäki[1,2,3*], Maija Satamo[2], Min Yang[4] and Tero Vahlberg[5]

## Abstract

**Background** Gaming interventions hold promising potential for methods of mental health treatment. Games designed for individuals with serious mental illness have demonstrated high acceptability. They have been shown to improve treatment engagement and increase a sense of self-efficacy and social integration. However, concerns remain over the potential adverse effects of regular gaming. Therefore, to investigate both the benefits and the risks, there is a need for well-designed, -conducted and -reported high-quality trials. This study aims to evaluate the effectiveness of a gaming intervention in improving functional and clinical outcomes in people with psychotic disorders and to assess the feasibility of the intervention.

**Methods** The effectiveness of the gaming intervention will be assessed using a controlled clinical trial with a pragmatic, multicentre, two-arm parallel-group design. The participants will be recruited from various types of outpatient units (e.g. outpatient psychiatric units, day hospitals, residential care homes). Following the baseline assessment, participants will be centrally randomised (1:1) to receive either the gaming intervention plus treatment as usual (TAU) or TAU alone. The primary outcome will be the change in social functioning, measured at 3- and 6-month follow-ups. The secondary outcomes will include the patients' major psychiatric symptoms, self-efficacy, quality of life, and aggression and potential adverse effects, also measured at 3 and 6 months. We will also test the feasibility of the gaming intervention from the perspectives of patients and nursing staff at a 3-month follow-up. Data will be collected from outpatient psychiatric services across Finland. Eligible participants will be between 18 and 60 years old and have a formal diagnosis of a psychotic disorder (F20–F29). We aim to recruit a total of 356 participants (178 for each group). We will estimate the efficacy of the intervention on the primary and secondary outcomes based on the intention-to-treat principle. Feasibility data will be analysed separately.

**Discussion** This study will be one of the first trials to address the effectiveness of video gaming on improving functional and clinical outcomes in people with schizophrenia. The study will offer new information to confirm both the benefits and possible disadvantages of using gaming to improve patients' health and well-being as new approaches to patient care in mental health services in Finland are explored. The results may provide insight into treatment for other health conditions in which motivational problems impact health outcomes.

**Trial registration** NCT05707689. Registered on 21 January 2023

*Correspondence:
Maritta Välimäki
maritta.valimaki@helsinki.fi
Full list of author information is available at the end of the article

**Keywords** Gaming, Randomised controlled trial, Schizophrenia, Psychotic disorder, Effectiveness

## Background

The overall aim of this study is to evaluate the impact of a gaming intervention on functioning in people with schizophrenia. This topic is important as schizophrenia is associated with poor psychosocial outcomes [1], including social withdrawal, apathy, and isolation [2], which often impair the ability of individuals to manage their daily activities [3]. As 15% of individuals with schizophrenia return to psychiatric hospitals after 1 month, and 20% experience a relapse within 1 year [4], schizophrenia is one of the most expensive mental disorders in terms of direct treatment costs and loss of productivity [5]. Therefore, there is an urgent need for novel, effective, and acceptable treatments to support patients with schizophrenia [6].

Evidence-based guidelines recommend medication and psychosocial interventions as the standard treatment for individuals with schizophrenia [7]. However, the effectiveness of these treatments is limited by patient nonadherence [8]. The American Psychiatric Association clinical guidelines [9] further recommend cognitive remediation (CR), which allows personalised interventions and individually adjusted modules [10]. However, the quality of the current evidence supporting CR is low (2C) [9]. CR interventions are expensive [11] and involve complex, heavily scheduled exercises [12], which leads to high drop-out rates [13]. There are also uncertainties regarding the optimal duration, approach, or dosage needed in the CR [14]. Furthermore, while the impact of CR is typically tested in laboratories, the real-life effects remain unclear [13]. Therefore, if similar results can be achieved with a simple, low-human intensity computer-based intervention, it would be worth using in practice.

Gaming interventions hold promising potential for methods of mental health treatment [15]. Entertaining video games have opened new avenues for remedial interventions targeting attention, problem-solving, emotional expression, and socialisation [16]. The acceptability of games as treatment for serious mental illness is high [17]. They can improve engagement in treatment [18] and increase a sense of self-efficacy and social integration [19]. A randomised multisite trial conducted by Nahum et al. [20] demonstrated the efficacy of a remote, plasticity-based social cognitive training programme in improving both social cognition and social functioning in individuals with schizophrenia. Another study found that entertainment games significantly improved adherence to e-interventions for people with psychosis, as these games incorporate 'rewards' or 'extra lives' that can be redeemed daily, thereby encouraging much needed engagement with services [21]. However, to facilitate synaptogenesis, repetitive high-dosage training is needed to produce the most effective approach [22]. On the other hand, concerns have been raised over the potential adverse effects of regular gaming activities. Likewise, our Cochrane review and meta-analysis [23] highlighted the importance of moderating the quantity of time spent on gaming for individuals with schizophrenia. Therefore, to investigate the potential benefits and risks of gaming, well-designed, -conducted and -reported high-quality trials are needed. In particular, a trial where gaming is the experimental group is warranted as evidence in this area remains severely limited [23].

### Objectives and hypotheses

The overall goal of this study is to evaluate the effectiveness of a gaming intervention to improve functioning and clinical outcomes in people with psychotic disorders. The feasibility of the intervention will also be assessed. Our hypotheses are as follows:

#### *Primary hypothesis*

(1) The gaming intervention will be more effective than treatment as usual (TAU) in improving functioning at 3- and 6-month follow-ups.

#### *Secondary hypotheses*

(2) The gaming intervention will be more effective than TAU in improving clinical outcomes and treatment acceptance (symptoms, self-efficacy, the quality of life, drop-out from intervention) at 3 and 6 months.
(3) The gaming intervention will not be associated with a higher incidence of adverse effects compared to TAU at 3-and 6-month follow-ups.

## Methods

### Trial design

The effectiveness of the gaming will be assessed using a controlled clinical trial with a multicentre, two-arm parallel-group design, with an allocation ratio of 1:1. The description of the methods to be used in the study has been guided by the SPIRIT guidelines [24]. The checklist can be found as an attachment (Additional file 1). Intervention elements in the experimental group are based

on the Template for Intervention Description and Replication (TiDier) checklist [25]. Feasibility will also be assessed. The study has been registered (NCT05707689, ClinicalTrials.Gov).

### Participants

The participants can join and/or withdraw the study based on their free will. Inclusion and exclusion criteria will be applied. Participants must meet the following inclusion criteria: (1) Fluent in Finnish, (2) have a formal diagnosis of a psychotic disorder (F20–F29, ICD-10, as identified in medical records or other reliable sources by staff), (3) aged between 18 and 60 years, (4) capable of participating in the study voluntarily, and (5) able to provide written informed consent. In cases of uncertainty regarding a participant's cognitive status, the 'judgement standard' will be used—that is, the mental status of the participants will be approved by the staff responsible for the treatment or services, based on their clinical expertise. Individuals with varying levels of gaming skills and experience are eligible for participation.

The exclusion criteria are as follows: (1) Meeting diagnostic criteria for a current major depressive, manic, or hypomanic episode or mental retardation (ICD-10); (2) having severe visual impairment; (3) signs or diagnosis of gaming addiction; (4) inability to make an independent decision to participate; (5) active substance abuse (other than nicotine dependence); (6) head injury, hemiplegia, or other neurological disorder; or (7) having received electroconvulsive therapy (ECT) in the past 6 months.

Participant eligibility will be assessed by the participating study organisations. Depending on the study organisations, the staff will determine eligibility based on patient registers or based on the staff's own expertise, familiarity with the patient, and interviews with the patient.

The Patient Health Questionnaire-9 (PHQ-9) [26] scores will also be used to ensure patient safety. For any measurement, if PHQ-9 scores are greater than 2 on the item related to suicide and self-harm, an alert will be sent to the participant's clinician. A participant may be withdrawn from the study if such action is recommended by their clinician.

### Setting

The study will be conducted in psychiatric outpatient organisations in Finland (e.g. outpatient psychiatric units, day hospitals, residential care homes). The data collection will begin in the Helsinki area.

### Interventions

Participants will be randomised into one of two groups: the gaming intervention group or the control group.

The gaming intervention will be conducted in small groups (6–10 participants), closely monitored by trained gaming facilitators. Pre-scheduled gaming sessions, about 60 min each, will be run twice a week over 10 weeks (totally 20 h) [23]. If needed, the gaming schedule will be tailored based on the participants' individual needs (work, studies, family issues) as long as the total gaming hours are achieved. Participants will be encouraged not to play video games during the study period. This restriction is feasible as only 20% of patients with schizophrenia engage in regular gaming [27]. Participants' gaming interventions will be closely monitored and recorded after each gaming session in a designated gaming diary. In case the participant cannot join the intervention session or the session is cancelled due to illness or another personal reason, a makeup session will be organised. A detailed description of the gaming intervention, following the TiDier checklist [25], is provided in Additional file 2.

Participants in the TAU group will receive standard planned care, with no additional activities organised for them by the research team.

### Outcomes

In selecting the outcomes for this study, we followed the recommendations outlined in the Cochrane review [23] to measure the effectiveness of gaming interventions for people with schizophrenia. For outcome assessment, data will be collected at baseline (T0), 3 months (T1), and 6 months (T2).

#### *Primary outcome*

Changes in functioning over the trial period will be assessed using the Personal and Social Performance Scale (PSP), which provides a global score [28]. The PSP is a brief, sensitive, professionally rated instrument used to assess functioning in individuals with schizophrenia. The instrument measures four domains: (a) socially useful activities, (b) personal and social relationships, (c) self-care, and (d) disturbing and aggressive behaviour. Each of the domains is rated with a single item using a 6-point scale (absent, mild, manifest but not marked, marked, severe, or very severe). A global item is rated by the interviewer, ranging from 1 to 100 in 10-point intervals, with lower scores indicating poorer functioning. The PSP has found an acceptable, quick, and valid measure of patients' personal and social functioning. In addition, it has demonstrated

excellent inter-rater reliability with an ICC of 0.98 and weighted kappa of 0.95 [28].

#### *Secondary outcomes*

*Psychiatric symptoms and functional impairment* Major psychiatric symptoms and functional impairment will be assessed using the Behavior and Symptom Identification Scale® (BASIS-24) [29]. The scale measures symptoms such as mood disturbances, anxiety, suicidality, and psychotic symptoms. The survey includes 24 items, structured based on six subscales (depression and functioning, relationships, self-harm, emotional liability, psychosis, substance abuse). Of the 24 items, the first 3 assess the degree of difficulty the respondent has experienced for each item during the past week with a 5-point Likert scale (0 = no difficulty, 1 = a little difficulty, 2 = moderate difficulty, 3 = quite a bit of difficulty, 4 = extreme difficulty). Nine items measure how much time during the past week each symptom or problem presented itself, using a 5-point Likert scale (0 = none of the time, 1 = a little of the time, 2 = half of the time, 3 = most of the time, 4 = all of the time). The remaining 12 items assess how often each symptom or behaviour occurred during the past week, with a 5-point Likert scale (0 = never, 1 = rarely, 2 = sometimes, 3 = often, 4 = always). Scores are computed for the overall scale, as well as for six subscales. The overall BASIS-24 score is calculated by multiplying each item's rating by its assigned weight and summing the weighted values. Similarly, each subscale score is derived by multiplying the ratings of the items within the subscale by their respective weights and then summing the results. However, there are no specified clinical cutoffs for the BASIS-24. Each subscale score, as well as the overall mean score, is calculated as the average of the weighted item scores and ranges from 0 to 4. A score of 0 represents the lowest level of self-reported symptoms or functional impairment, while a score of 4 represents the highest level. The BASIS-24 has shown good reliability and validity to assess functioning and mental health from the client's perspective with well-established psychometric properties: test–retest reliability ranged from 0.75 to 0.89 for inpatients and 0.77 to 0.91 for outpatients [30].

*Depressive symptoms* The PHQ-9 [26] will be used to assess the severity of depression. Respondents are asked to indicate how often they have experienced a specific topic during the last week using 4-point scale (0 = not at all, 1 = several days, 2 = more than half of the days, 3 = nearly every day). The total score of this self-administered questionnaire is calculated by summing the value for all nine items, yielding a score ranging from 0 to 27, where a higher score represents a greater severity of depression. In addition, depression severity can be categorised into five levels: 0–4 (none), 5–9 (mild), 10–14 (moderate), 15–19 (moderately severe), and 20–27 (severe). Test–retest reliability of the PHQ-9 has been found to be excellent, with ICCs between 0.81 and 0.96 [31].

*Self-efficacy* Self-efficacy will be assessed using the General Self-Efficacy Scale (GSE) [32], a 10-item self-report instrument (1 = not at all true, 2 = hardly true, 3 = moderately true, 4 = exactly true) designed to measure optimistic self-beliefs in coping with a variety of difficult demands in life. Items 1–10 are summed to create a composite score ranging from 10 to 40, where a higher score represents greater perceived self-efficacy. In samples from 23 nations, Cronbach's alphas ranged from 0.75 to 0.90, with the majority in the high 0.80 s [33].

*Quality of life* Quality of life will be assessed using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) [34], a self-report measure designed to sensitively measure the degree of enjoyment and satisfaction respondents experience in various areas of daily functioning. A total quality of life score is derived by summing all 15 items, resulting in a maximum of 70 points. In addition, two global items, rating satisfaction with study medication and overall life satisfaction, are scored separately. The total scored is expressed as a percentage of the total possible score, with higher scores indicating better health status. The internal consistency and test–retest coefficients were 0.9 and 0.93, respectfully, and almost all items significantly correlated to the total score indicating that the instrument could produce reliable and valid clinical assessments of quality of life [35].

*Engagement* Engagement will be recorded based on participants withdrawing from the intervention (yes/no) or the study (yes/no).

Adverse effects (harms) during intervention are defined as any unfavourable medical occurrence in a study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, which is temporally associated with a participant's involvement in the research, regardless of whether they are considered related to participation in the research (NIA Guidelines) [36]. The data about harms of health interventions are important in clinical trials to allow patients and healthcare providers to make truly informed decisions [37]. In this study, the specific adverse effects (harms) will be categorised as follows:

a) Relapse (increased dosage or additional medicines prescribed) [38],

b) An exacerbation of psychotic symptoms leading to any change in patient management to be identified by staff members
c) Admission to psychiatric hospital (yes/no, number of admissions up to 6-month follow-up, total number of hospital days)
d) Any violent incidents necessitating staff involvement that target another person or property, whether the participant is the victim or the aggressor [39],
e) Self-harming behaviour and suicide (includes attempt)
f) Aggression at baseline was measured at 3 and 6 months using the Buss-Perry Aggression Questionnaire-Short Form (BPAQ-SF) [40] with 12 items using true-or-false-type questions assessing anger, physical aggression, hostility, and verbal aggression (internal consistency of the subscales based on Spearman-Brown-adjusted Cronbach's alpha 0.88–0.92 [40]
g) Mortality [41].

To assess the implementation process of the intervention, as well as its feasibility, fidelity, acceptability, and appropriateness, the following methods will be employed:

1) Implementation process: To evaluate how this novel intervention is implemented into existing health services, an organisational analysis will be conducted using the main domains of the Consolidated Framework for Implementation Research (CFIR) [42]. Interviews will be conducted with staff members from the participating organisations. The CFIR comprises five major domains (and specific constructs) that affect how an intervention is implemented into practice: (1) Intervention characteristics (e.g. intervention source, evidence strength and quality, relative advantage), (2) outer setting (e.g. patient needs and resources, peer pressure, external policies, and incentives), (3) inner setting (e.g. structural characteristics, culture, implementation climate), (4) characteristics of the individuals involved (e.g. knowledge and beliefs about the intervention, self-efficacy, individual stage of change), and (5) process of implementation (e.g. planning, engaging, executing). This construct will guide our assessment of how successful the intervention was regarding how it was planned, organised, scheduled, monitored, and evaluated at specific time points (see Fig. 1).
2) Feasibility: Feasibility will be assessed by calculating the patient refusal rate and recruitment flow and by assessing the reasons for refusal and reasons for drop-out, according to the study records. In addition, the Feasibility of Intervention Measure (FIM) [43], an instrument with four items, will be used to assess the feasibility of the intervention.
3) Fidelity: Intervention fidelity will be assessed by calculating the number of intervention sessions delivered (out of 20), the total intervention time (in hours out of 20 h), and the quality of the intervention sessions based on the content of the diaries.
4) Acceptability: The acceptability of the intervention will be assessed by the participants using a 4-item survey instrument, the Acceptability of Intervention Measure (AIM) [43].

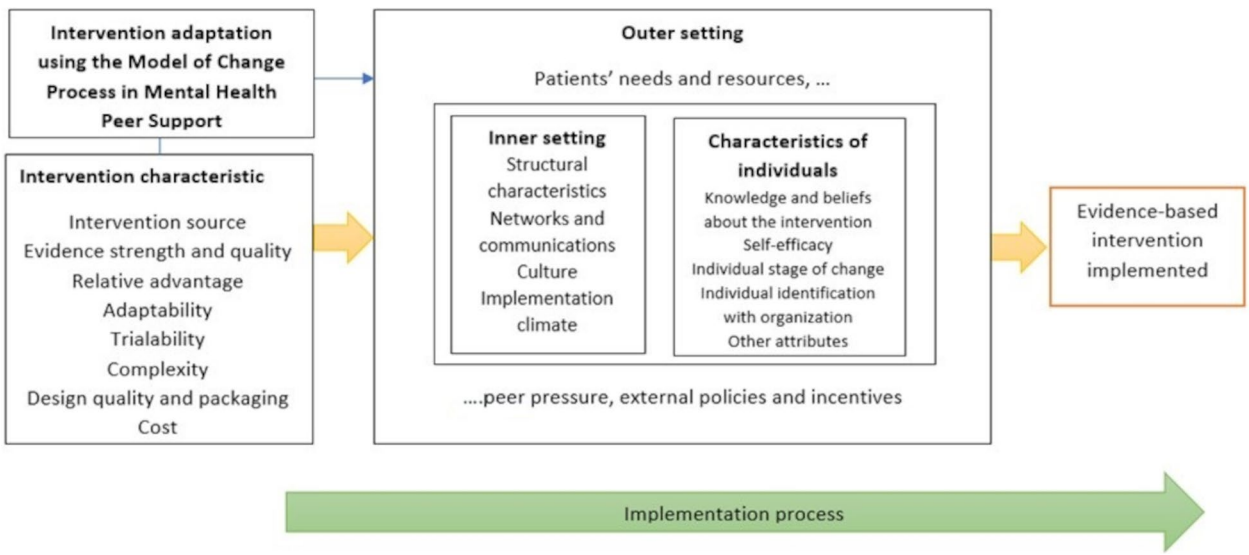


**Fig. 1** Assessment of the intervention implementation process. Modified based on Damschroder et al. [42]

5) Appropriateness: The appropriateness of the intervention will be evaluated using a short survey instrument, the Intervention Appropriateness Measure (IAM) [43], which will be administered to the participants and the facilitators.

A summary of the outcomes, instruments, and specific timelines are described in Fig. 2.

### Sample size

Using the trial by Lahera et al. [44] as a reference, we assume a mean difference of 3.7 points in the change in PSP scores ($SD = 14$) between the intervention and control groups at the end of the study period. To detect a 3.7-point mean difference in change between groups assuming SD of 11.4 for change using two-sided test and 80% power, the required sample size is 150 participants per each group; in total, 300 participants are needed. Based on our preliminary study related to cognitive gaming, we assume that about 16% patients will drop-out of the current study. To compensate the drop-out, we estimated a sample of 356 cases in total 178 in each group. If 70% refuse and 67% are eligible, about 2100 patients should be screened for eligibility.

| | STUDY PERIOD | | | |
|---|---|---|---|---|
| | Enrolment | Allocation | Post-allocation | |
| **TIMEPOINT** | $-t_1$ | 0 | $t_1$ | $t_2$ |
| **ENROLMENT:** | | | | |
| Eligibility screen | X | | | |
| Informed consent | X | | | |
| Allocation | | X | | |
| **INTERVENTIONS:** | | | | |
| Experiment group | | ● | ● | |
| Usual practice (TAU) | | ● | ● | |
| **OUTCOME ASSESSMENTS:** | | | | |
| **Baseline** | | | | |
| Characteristics of the participants | X | | | |
| **Feasibility outcomes** | | | | |
| ***Primary outcome*** | | | | |
| *Functioning, PSP* | X | | X | X |
| ***Secondary outcomes*** | | | | |
| *Major mental health symptoms, BASIS-24* | X | | X | X |
| *Depressive symptoms, PHQ-9* | X | | X | X |
| *Self-efficacy, GSE* | X | | X | X |
| *Quality of life, Q-LES-Q* | X | | X | X |
| *Aggression, BPAQ-SF* | X | | X | X |
| *Engagement* | | | X | |
| **Assessment of the intervention** | | | | |
| *Implementation (staff only)* | | | X | |
| *Feasibility, record analysis and FIM* | | | X | |
| *Fidelity, analysis of gaming diaries* | | | X | |
| *Acceptability, AIM* | | | X | |
| *Appropriateness, IAM* | | | X | |

**Fig. 2** Outcomes, instruments and specific timelines for outcome assessment using SPIRIT [24]

### Recruitment

Potential participants will be identified and screened according to the inclusion criteria with the assistance of a designated contact person at each study organisation. Researchers will not have access to the personal records or patient documents maintained by the organisations. To facilitate recruitment and minimise the workload for staff, a research assistant will work onsite at the study organisations. The assistant will provide detailed oral and written information about the study to eligible individuals. The data collection may be expanded to other organisations and cities if necessary to achieve the required sample size.

### Data collection

The Ethics Committee of the Wellbeing Services County of Southwest Finland has reviewed the GAME-A study proposal and has issued a positive statement on the research plan (reference codes ETMK 53/1801/2022 and VARHA/5746/13.02.02/2023). Permission to conduct the study will be obtained from all participating organisations. The general principles outlined in the Declaration of Helsinki [45] and local ethical regulations will guide the practical arrangements of the study. Guidance from the Finnish National Board on Research Integrity will be followed to ensure the responsible conduct of research and the prevention research misconduct [46].

Eligible participants will be personally invited by the research assistants to consider participation in the study. Each research personnel member will receive centralised training on the study requirements through a total of 4 h of hands-on training sessions. These sessions will cover topics such as the use of instruments, obtaining informed consent, data collection procedures, safety issues, voluntariness, and the right to withdraw from the study, among others. Upon reviewing the provided information, participants may provide informed consent using a paper-based form. After providing consent, participants will complete a background survey and baseline questionnaire, also in paper format.

Under Finnish law, no compensation can be paid to the study participant, their guardian, close relative, other close associate, or legal representative for participating in the study. However, reasonable compensation may be provided for costs incurred, loss of earnings, or other inconveniences resulting from the study (Medical Research Act, 488/1999, Section 21) [47]. Insurance as defined in Section 1 of the Patient Insurance Act (948/2019) covers any potential damages caused by the study in accordance with the Patient Insurance Act [48]. Liability for damages is regulated by the Tort Liability Act (412/1974, Section 23) [49]. The employer is obligated to compensate for damages caused by an employee's error or negligence in the course of their work (Chapter 3, Section 1). Therefore, in this study, to promote participant recruitment, possible travel costs incurred due to the study will be reimbursed. Participant retention and upcoming follow-up data collection will be supported with text message reminders and emails. Additionally, appointments will be scheduled based on participants' availability. Participant retention will be carefully monitored.

To ensure safety, the well-being of the participants will be closely monitored throughout the intervention. If a participant shows any sign of deteriorating mental status—identified by the nursing staff or the research assistant through daily monitoring or diaries, or if a participant has a score greater than 2 on the suicide and self-harm item of the PHQ-9 any measurement point, protective measures will be initiated. An alert will be sent to the participant's clinician, and their status will be managed in accordance with the clinical governance protocols. The research personnel will not offer any crisis support to participants; any worries identified by the investigators will be reported immediately to the staff members. If deemed necessary by the clinician, the participant will be withdrawn from the study.

To evaluate the feasibility of the study, nursing staff will be invited to participate by completing a short electronic questionnaire. The invitation email will be distributed by a contact person and will include information about the study, along with a link to more details about the study and the questionnaire via Research Electronic Data Capture (REDCap) [50], tools, which is hosted by the University of Turku. After reviewing the information provided, participants may give their informed consent electronically. Following consent, nursing staff will be asked to complete an electronic questionnaire to provide background information about the participants. At the end of the survey, nursing staff will be asked if they are willing to take part in a short interview to share their experiences regarding the implementation of the intervention. Those interested in participating will be asked to provide their email address in a dedicated field within the REDCap system. A research assistant will then reach out to schedule the interview, which will be conducted via Teams.

Important protocol modifications will be communicated to relevant parties, including the Ethical Review Board and study organisations. Any modifications will be reported in the trial registry (ClinicalTrials.gov) and in the final report.

An overview of the trial profile is described in Fig. 3.

### Interim analyses and stopping rules

An interim analysis will be conducted approximately halfway through the data collection period. The results

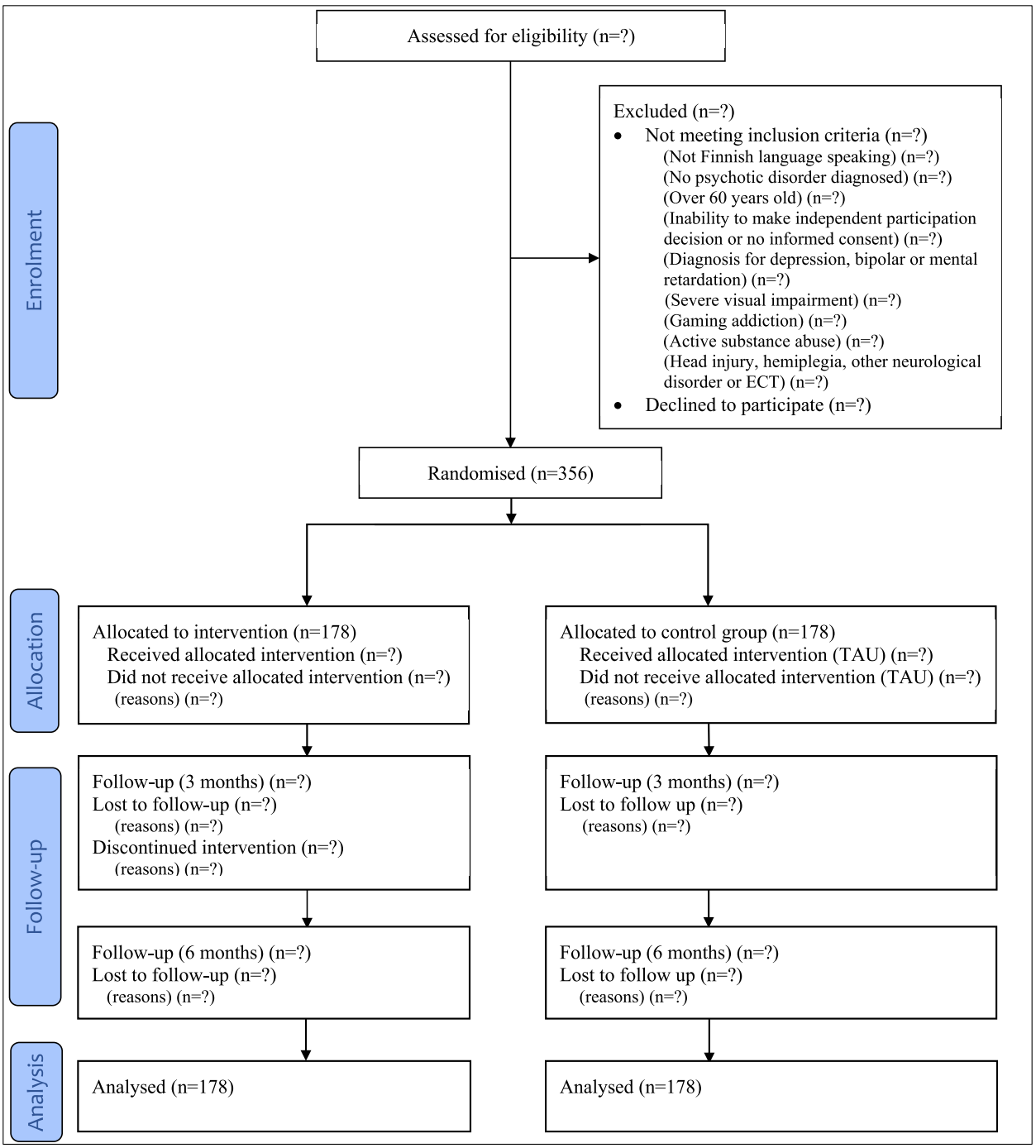


**Fig. 3** Flow chart [51]

will be shared and discussed with the Data Management Committee, which is an independent group separate from the sponsor and has no competing interests [52]. Its six members represent different disciplines and areas: psychiatry, patient association, health services, and statistics. The interim results will also be shared with the Data Management Committee. Only study investigators, i.e. the principal investigator (PI) (M. V.), researcher (M. S.), and statisticians (T. V., M. Y.), will have access to the data. The role of the committee is to ensure the quality of the data, data collection, data privacy, safety of the intervention, incorporation of participant feedback, and

data analysis and provide further recommendations for the study. Although it is uncertain exactly how much evidence of harm should be required over benefits of the study, no specific stopping rules have been established a priori for the trial [53]. Therefore, the study can be terminated based on input from staff members and especially representatives of patient associations. However, the final decision to stop the trial will be made by the Data Management Committee.

#### Randomisation

Participants will be centrally randomised (1:1) after baseline assessment into either the gaming intervention plus TAU group or the group to receive TAU alone. The randomisation list will be computer-generated by an external independent clinical trial statistician at the University of Turku. Randomisation will be balanced using randomly permuted blocks. A trial assistant outside the research team will enrol the participants, and a research assistant will assign participants into the groups. Statisticians will be masked. Gaming facilitators and staff working at the study sites will not be masked. Code breaks will occur only in exceptional circumstances, for example, if during the analysis, the statisticians indicate any harm in patient data scores. However, this will be done only after discussions with the Data Management Committee and based on their recommendations.

#### Data management and statistical methods

All data will be processed in accordance with the European Union's (EU) General Data Protection Regulation 2016/679 [54]. The research data will not be transferred to another register or to another personal data processor. The quality of the data will be ensured through the use of double data entry. The research data will not be shared to anyone outside the research team, even if requested. The research data will be used only in this research. The data will be collected with the participants' informed consent. The participants will have the right to withdraw from the study, to access their personal data, to demand that their data is rectified or deleted, to restrict the processing of personal data, and to lodge a complaint if they believe a violation of applicable data protection laws has taken place [54].

Participants will be informed that their personal data may be processed during inspections by domestic or foreign authorities, regular quality control of the research by a research monitor who is not part of the research team, and/or quality assurance activities conducted by a representative of the commissioner.

All study-related information will be stored securely at the study sites and research office. All participant information will be stored in locked file cabinets in areas with limited access or researchers only. All reports, data collection, process, and administrative forms will be identified by a coded ID number only to maintain participant confidentiality. All records that contain names or other personal identifiers (informed consent forms, gaming, diaries) will be archived separately from study records identified by code number. All databases will be secured with password-protected codes. Any data for monitoring purposes (appointment books, data monitoring excel) linking participant ID numbers to other identifying information will be stored in a separate, locked file. Baseline and follow-up data collected from the participants in paper format will be scanned and stored in a secure cloud storage service provided by the IT services of University of Turku, with access restricted through password protection. The electronic feasibility data collected from nursing staff will be managed with REDCap, a secure, web-based software platform used to conduct research studies [50].

Descriptive analysis will be performed, subscale scores will be formed, and the means (standard deviation, SD) of the appropriate items will be calculated at each time point by trial group. Outcomes will be examined by level of covariates between treatment groups. Covariates significant difference in outcomes by treatment groups indicate potential confounders that should be adjusted for in testing the intervention effects. All analyses will be conducted following the intention-to-treat principle. Mechanism of the missing data will be assessed with multiple ways. Differences between participants and those who have withdrawn from the study will be analysed by comparing background variables (age, gender, education level, etc.) using logistic regression analysis for binary data (missing or not missing). Possible duplicate measurements will be identified based on procedures during the screening period, using participant initials, ID codes, or records maintained by nursing staff and research personnel. The multiple imputation of missing data would be considered when appropriate.

For the primary outcome, we will report the mean (SD) of the PSP global score at each time point and calculate mean change with 95% confidence interval from the baseline to the 3-month and 6-month follow-up for each group. Based on the descriptive analysis, the linear mixed models (LMM) will be used to test changes in PSP from the baseline to 3 and 6 months, with adjustment for potential confounders. The model will include the main effects of treatment group, the interaction between treatment group and follow-up time of 3 and 6 months as fixed effects, and include random intercept effects among study centres and among patients. The difference in mean change between the two groups will be estimated from the model using estimated marginal means (EMM) with

95% CI and tested using generalised Ward test. Since this method tests the mean change scores at 3 and 6 months between intervention groups simultaneously, no multiple comparison issue occurs in this case. However, if the assumptions for normality of residuals in the model are not met, the commonly used data transformations (e.g. log, square root, inverse) may be considered prior to the final model analysis.

All secondary outcomes are continuous scores and will be analysed using the same method as for the primary outcome.

Sensitivity analysis will be carried out to understand (1) the impact of missing data on the intervention effects and (2) the possible modifying effects of important covariates such as age, gender, number of gaming hours played, and active/passive gaming experience on the effectiveness of intervention.

Statistical analyses will be carried out with SPSS IBM 29, SAS System for Windows, version 9.4 (SAS Institute Inc.) or R statistical software (R Core Team, 2016). In the statistical analyses, *p*-values less than 0.05 will be considered as statistically significant, and two-sided tests will be used.

## Discussion

The study will generate novel information on the effectiveness and feasibility of a gaming intervention for individuals with serious mental health conditions. The study will answer complex clinical questions using a simple, efficient, easy to organise, and low-intensity intervention. The trial has been designed to offer new results quickly and timely. Self-measured questionnaires and robust objective research methods will be combined to provide the best possible understanding of the outcomes.

Our intervention is based on existing technology. It is easy to use, engaging, and low in cost, which ensures its sustainability and scalability in other treatment settings and patient groups. If effective, the intervention can be used with many patient groups facing challenges related to cognitive problems, deficits in decision-making, and engagement in treatment (e.g. elderly care, young boys with social problems). The study will offer a structured model to monitor and ensure safe health technology practices. The study results will also be applicable in any treatment setting where a new intervention is to be implemented into daily practice. Most importantly, this is the first trial to carefully analyse the feasibility and potential adverse effects of a gaming intervention. Stakeholder representation has been carefully considered as their views add important value to the study; they have already expressed their opinions on the most valuable outcome to be assessed in the study. A stakeholder representative will also serve as a member of our research team to support the accuracy of the study.

The findings from this study have the potential to inform policymakers on the value of simple, low-cost, engaging, low-intensity, and scalable interventions in addressing the clinical, economic, and organisational problems related to patients with serious mental health conditions in their transition from hospital back into a community setting. By adopting an implementation science approach, the study can offer a model for how any new technology-based intervention can be implemented into routine care, promoting the sustainability of the intervention. The study is also expected to produce new interdisciplinary and multidisciplinary cooperation.

## Trial status

The study was first submitted on 21 January 2023 (ClinicalTrials.gov NCT05707689). Recruitment started on 6 February 2023. Recruitment will be completed by 31 December 2026. This is version 1.0 of the full study protocol, dated 30 June 2025.

## Dissemination

Substantive contributions of each author to the design, conduct, interpretation, and reporting of the clinical trial have been recognised through the granting of authorship on the study protocol. All authors of the protocol manuscript have read and agreed to its content and are accountable for all aspects of the accuracy and integrity of the manuscript, in accordance with the International Committee of Medical Journal Editors (ICMJE) criteria.

The study results will be reported and published in scientific and professional journals, as well as presented at conferences. In the final trial report, the contributions of each author will be confirmed and recognised. All authors of the manuscript will read and agree to its content, and they will be accountable for all aspects of the accuracy and integrity of the trial report manuscript, in accordance with ICMJE criteria. Ghost authorship will not be used. A professional expert in English language editing has been used for the study protocol and will be used for the final trial report.

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-026-09456-2.

Additional file 1: SPIRIT Checklist for Trials [24].

Additional file 2: Description of the gaming intervention in the experimental group according to the Template for Intervention Description and Replication (TIDier) checklist [25].

**Acknowledgements**
We would like to thank the state research funding in the Wellbeing Services County of Southwest Finland (Varha) (project code 30004, 2023–2024); the University of Turku, Finland, internal funding (26002441); the University of Helsinki, Finland (73715712); Helsinki University Library; the Doctoral Programme in Nursing Science (DPNurs/UTUGS, 2024–2026); the University of Turku, Finland (TY/197/2023); and the TYKS Foundation for making this study possible. We also want to express our gratitude to Leigh Ann Lindholm, who has reviewed the English language in the manuscript.

**Authors' contributions**
MV initiated the study. MV and MS received the grants for the study. MV developed the general study design and managed the study. MY and TV planned the statistical analysis plan for the study and how to interpret the data. MV and MY drafted the protocol, and MS and TV contributed to the protocol by commenting on and editing the protocol draft. All authors (MV, MS, MY, TV) joined in the decision to submit the protocol for publication.

**Funding**
Open Access funding provided by University of Helsinki (including Helsinki University Central Hospital). This study is funded by the state research funding in the Wellbeing Services County of Southwest Finland (Varha) (project code 30004, 2023–2024); the University of Turku, Finland, internal funding (26002441); and the University of Helsinki, Finland (73715712), obtained by M. V. In addition, the study has been supported by the Doctoral Programme in Nursing Science (DPNurs/UTUGS, 2024–2026); the University of Turku, Finland (TY/197/2023); and the TYKS Foundation, obtained by M. S. Open access funded by Helsinki University Library. The funding bodies will not gain or lose financially from the publication of this manuscript now or in the future. The funding bodies have not participated in the design of the study or in writing the current manuscript, and they will not participate in the collection, analysis, or interpretation of the data.

**Data availability**
The data will be collected for the purpose of this study only. As approved by the Ethics Committee of the Wellbeing Services County of Southwest Finland (reference codes ETMK 53/1801/2022 and VARHA/5746/13.02.02/2023), the individual patient data will not be shared with other researchers. Metadata describing the study (a general description) will be available.

## Declarations

**Ethics approval and consent to participate**
The Ethics Committee of the Wellbeing Services County of Southwest Finland has reviewed the GAME-A study proposal and issued a positive statement on the research plan (reference codes ETMK 53/1801/2022 and VARHA/5746/13.02.02/2023). Permission to conduct the study will be obtained from all participating organisations. All participants will provide written informed consent before data collection at baseline. Nursing staff will provide electronic informed consent before data collection via the survey and interviews. Participants will be informed that they have the possibility to withdraw their consent, and they will be made aware that data collected before withdrawal may be used for research purposes. Participants will also be informed about the confidentiality of the collected data and assured that refusal to participate or withdrawal from the study will not affect their status within service organisations.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare that they have no competing interests.

**Author details**
[1]Department of Public Health, Helsinki University Hospital, Nursing Research Center (NRC), University of Helsinki, Helsinki 00014, Finland. [2]Faculty of Medicine, Department of Nursing Science, University of Turku, Turku 20014, Finland. [3]The Wellbeing Services County of Southwest Finland, Turku 20521, Finland. [4]Faculty of Health, Art and Design, Swinburne University of Technology, Melbourne, VIC 3122, Australia. [5]Department of Biostatistics, University of Turku and Turku University Hospital, Turku 20014, Finland.

**Received: 30 June 2025 Accepted: 12 January 2026**
Published online: 21 January 2026

**References**

1. Morgan C, Lappin J, Heslin M, et al. Reappraising the long-term course and outcome of psychotic disorders: the AESOP-10 study. Psychol Med. 2014;44(13):2713–26. https://doi.org/10.1017/S0033291714000282.
2. Galderisi S, Mucci A, Buchanan RW, et al. Negative symptoms of schizophrenia: new developments and unanswered research questions. Lancet Psychiatry. 2018;5(8):664–77. https://doi.org/10.1016/S2215-0366(18)30050-6.
3. Green MF, Kern RS, Braff DL, Mintz J. Neurocognitive deficits and functional outcome in schizophrenia: are we measuring the "right stuff"? Schizophr Bull. 2000;26:119–36. https://doi.org/10.1093/oxfordjournals.schbul.a033430.
4. Rubio JM, Schoretsanitis G, John M, et al. Psychosis relapse during treatment with long-acting injectable antipsychotics in individuals with schizophrenia-spectrum disorders: an individual participant data meta-analysis. Lancet Psychiatry. 2020;7(9):749–61. https://doi.org/10.1016/S2215-0366(20)30264-9.
5. Dolder CR, Lacro JP, Jeste DV. Adherence to antipsychotic and nonpsychiatric medications in middle-aged and older patients with psychotic disorders. Psychosom Med. 2003;65(1):156–62. https://doi.org/10.1097/01.psy.0000040951.22044.59.
6. Owen MJ, Sawa A, Mortensen PB. Schizophrenia. Lancet. 2016;388(10039):86–97. https://doi.org/10.1016/S0140-6736(15)01121-6.
7. NICE. Surveillance report 2017 – Psychosis and schizophrenia in adults: prevention and management (2014) NICE guideline CG178. 2017. https://www.nice.org.uk/guidance/cg178/resources/surveillance-report-2017-psychosis-and-schizophrenia-in-adults-prevention-and-management-2014-nice-guideline-cg178-pdf-6041007637189. Accessed 14 Sep 2022.
8. Aleman A, Enriquez-Geppert S, Knegtering H, et al. Moderate effects of noninvasive brain stimulation of the frontal cortex for improving negative symptoms in schizophrenia: meta-analysis of controlled trials. Neurosci Biobehav Rev. 2018;89:111–8. https://doi.org/10.1016/j.neubiorev.2018.02.009.
9. Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia. Am J Psychiatry. 2020;177:868–72. https://doi.org/10.1176/appi.ajp.2020.177901.
10. Genevsky A, Garrett CT, Alexander PP, et al. Cognitive training in schizophrenia: a neuroscience-based approach. Dialogues Clin Neurosci. 2010;12(3):416–21. https://doi.org/10.31887/DCNS.2010.12.3/agenevsky.
11. Patel A, Knapp M, Romeo R, et al. Cognitive remediation therapy in schizophrenia: cost-effectiveness analysis. Schizophr Res. 2010;120(1–3):217–24. https://doi.org/10.1016/j.schres.2009.12.003.
12. Fisher M, Holland C, Merzenich MM, Vinogradov S. Using neuroplasticity-based auditory training to improve verbal memory in schizophrenia. Am J Psychiatry. 2009;66(7):805–11. https://doi.org/10.1176/appi.ajp.2009.08050757.
13. Keefe RS, Vinogradov S, Medalia A, et al. Feasibility and pilot efficacy results from the multisite Cognitive Remediation in the Schizophrenia Trials Network (CRSTN) randomized controlled trial. J Clin Psychiatry. 2012;73(7):1016–22. https://doi.org/10.4088/JCP.11m07100.
14. Reddy LF, Horan WP, Jahshan C, et al. Cognitive remediation for schizophrenia: a review of recent findings. Curr Treat Options Psychiatry. 2014;1(2):121–33. https://doi.org/10.1007/s40501-014-0011-8.
15. Shams TA, Foussias G, Zawadzki JA, et al. The effects of video games on cognition and brain structure: potential implications for neuropsychiatric disorders. Curr Psychiatry Rep. 2015;17(9):71. https://doi.org/10.1007/s11920-015-0609-6.
16. Horne-Moyer HL, Moyer BH, Messer DC, Messer ES. The use of electronic games in therapy: a review with clinical implications. Curr Psychiatry Rep. 2014;16(12):520. https://doi.org/10.1007/s11920-014-0520-6.

17. Fitzgerald M, Ratcliffe G. Serious games, gamification, and serious mental illness: a scoping review. Psychiatr Serv. 2020;71(2):170–83. https://doi.org/10.1176/appi.ps.201800567.
18. Nahum M, Fisher M, Loewy R, et al. A novel, online social cognitive training program for young adults with schizophrenia: A pilot study. Schizophr Res Cogn. 2014;1(1):e11–9. https://doi.org/10.1016/j.scog.2014.01.003.
19. Kimhy D, Khan S, Ayanrouh L, et al. Use of active-play video games to enhance aerobic fitness in schizophrenia: feasibility, safety, and adherence. Psychiatr Serv. 2016;67(2):240–3. https://doi.org/10.1176/appi.ps.201400523.
20. Nahum M, Lee H, Fisher M, et al. Online social cognition training in schizophrenia: A double-blind, randomized, controlled multi-site clinical trial. Schizophr Bull. 2021;47(1):108–17. https://doi.org/10.1093/schbul/sbaa085.
21. O'Hanlon P, Aref-Adib G, Fonseca A, et al. Tomorrow's world: current developments in the therapeutic use of technology for psychosis. BJ Psych Adv. 2016;22(5):301–10. https://doi.org/10.1192/apt.bp.115.014654.
22. Bavelier D, Achtman RL, Mani M, Föcker J. Neural bases of selective attention in action video game players. Vision Res. 2012;61:132–43. https://doi.org/10.1016/j.visres.2011.08.007.
23. Roberts MT, Lloyd J, Välimäki M, et al. Video games for people with schizophrenia. Cochrane Database Syst Rev. 2021;2:CD012844. https://doi.org/10.1002/14651858.CD012844.pub2.
24. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, et al. Spirit 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586. https://doi.org/10.1136/bmj.e7586.
25. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687. https://doi.org/10.1136/bmj.g1687.
26. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606–13. https://doi.org/10.1046/j.1525-1497.2001.016009606.x.
27. Välimäki M, Kuosmanen L, Hätönen H, et al. Connectivity to computers and the internet among patients with schizophrenia spectrum disorders: a cross-sectional study. Neuropsychiatr Dis Treat. 2017;13:1201–9. https://doi.org/10.2147/NDT.S130818.
28. Morosini PL, Magliano L, Brambilla L, Ugolini S, et al. Development, reliability and acceptability of a new version of the DSM-IV social and occupational functioning assessment scale (SOFAS) to assess routine social functioning. Acta Psychiatr Scand. 2000;101:323–9. https://doi.org/10.1034/j.1600-0447.2000.101004323.x.
29. Eisen SV, Normand SL, Belanger AJ, et al. The Revised Behavior and Symptom Identification Scale (BASIS-R): reliability and validity. Med Care. 2004;42:1230–41. https://doi.org/10.1097/00005650-200412000-00010.
30. CDP. Behavior and Symptoms Identification Scale (BASIS). 2025. Center for Deployment Psychology. Uniformed Services University of the Health Sciences. https://deploymentpsych.org/sites/default/files/member_resource/COP_Toolkit/Metrics_Series-Behavior_and_Symptom_Identification_Scale_BASIS.pdf. Accessed 30 May 2025.
31. Löwe B, Unützer J, Callahan CM, et al. Monitoring depression treatment outcomes with the patient health questionnaire-9. Med Care. 2004;42(12):1194–201. https://doi.org/10.1097/00005650-200412000-00006.
32. Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston M, editors. Measures in health psychology: A user's portfolio. Causal and control beliefs. Windsor, UK: NFER-NELSON; 1995. p. 35–7.
33. APA. General Self-Efficacy Scale. 2023. APA PsychNet. https://doi.org/10.1037/t00393-000. Accessed 19 Jan 2026.
34. Endicott J, Nee J, Harrison W, Blumenthal R. Quality of life enjoyment and satisfaction questionnaire: a new measure. Psychopharmacol Bull. 1993;29(2):321–6.
35. Stevanovic D. Quality of life enjoyment and satisfaction questionnaire-short form for quality of life assessments in clinical practice: a psychometric study. J Psychiatr Ment Health Nurs. 2011;18(8):744–50. https://doi.org/10.1111/j.1365-2850.2011.01735.x.
36. OHRP. Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance. 2007. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html. Accessed 14 Sep 2022.
37. Junqueira DR, Zorzela L, Golder S, et al. CONSORT harms 2022 statement, explanation, and elaboration: updated guideline for the reporting of harms in randomised trials. BMJ. 2023;381:e073725. https://doi.org/10.1136/bmj-2022-073725.
38. Buck B, Scherer E, Brian R, et al. Relationships between smartphone social behavior and relapse in schizophrenia: A preliminary report. Schizophr Res. 2019;208:167–72. https://doi.org/10.1016/j.schres.2019.03.014.
39 Macfadden W, DeSouza C, Crivera C, et al. Assessment of effectiveness measures in patients with schizophrenia initiated on risperidone long-acting therapy: the SOURCE study results. BMC Psychiatry. 2011;14(11):167. https://doi.org/10.1186/1471-244X-11-167.
40. Bryant FB, Smith BD. Refining the architecture of aggression: a measurement model for the Buss-Perry Aggression Questionnaire. J Res Pers. 2001;35:138–67. https://doi.org/10.1006/jrpe.2000.2302.
41. Jeppesen UN, Due AS, Mariegaard L, et al. Face your fears: Virtual reality-based cognitive behavioral therapy (VR-CBT) versus standard CBT for paranoid ideations in patients with schizophrenia spectrum disorders: a randomized clinical trial. Trials. 2022;23:658. https://doi.org/10.1186/s13063-022-06614-0.
42. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50. https://doi.org/10.1186/1748-5908-4-50.
43. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12(1):108. https://doi.org/10.1186/s13012-017-0635-3.
44. Lahera G, Reboreda A, Vallespí A, et al. Social cognition and interaction training (SCIT) versus training in affect recognition (TAR) in patients with schizophrenia: a randomized controlled trial. J Psychiatr Res. 2021;142:101–9. https://doi.org/10.1016/j.jpsychires.2021.07.029.
45. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191–4. https://doi.org/10.1001/jama.2013.281053.
46. TENK. The Finnish Code of Conduct for Research Integrity and Procedures for Handling Alleged Violations of Research Integrity in Finland. 2023. Finnish National Board on Research Integrity TENK. https://tenk.fi/sites/default/files/2023-11/RI_Guidelines_2023.pdf. Accessed 20 Mar 2023.
47. Medical Research Act, 488/1999. https://www.finlex.fi/fi/lainsaadanto/saadoskokoelma/1999/488. Accessed 19 Jan 2026. (in Finnish)
48. Patient Insurance Act, 948/2019. https://finlex.fi/en/legislation/translations/2019/eng/948. Accessed 30 May 2025.
49. Tort Liability Act, 412/1974. https://www.finlex.fi/fi/lainsaadanto/1974/412. Accessed 30 May 2025. (in Finnish)
50. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform. 2019;95:103208. https://doi.org/10.1016/j.jbi.2019.103208.
51. Hopewell S, Chan AW, Collins GS, et al. Consort 2025 statement: updated guideline for reporting randomised trials. Lancet. 2025;405:1633–40. https://doi.org/10.1016/S0140-6736(25)00672-5.
52. Grant AM, Altman DG, Babiker AB, et al. Issues in data monitoring and interim analysis of trials. Health Technol Assess. 2005;9(7):1–238. https://doi.org/10.3310/hta9070.
53. Tyson JE, Pedroza C, Wallace D, et al. Stopping guidelines for an effectiveness trial: what should the protocol specify? Trials. 2016;17(1):240. https://doi.org/10.1186/s13063-016-1367-4.
54. General Data Protection Regulation (EU) 2016/679 of the European Parliament and of the Council. https://eur-lex.europa.eu/eli/reg/2016/679/oj. Accessed 14 Sep 2022.


## Publisher's Note