Received: 21 November 2024 | Revised: 21 December 2024 | Accepted: 26 January 2025

DOI: 10.1002/pcn5.70065

PCN Reports
Psychiatry and Clinical Neurosciences
Open Access

PROTOCOL

Movie- and mobile-therapy without therapist involvment for patients with obsessive–compulsive disorder: Protocol for a randomized controlled trial

Hissei Imai MD, PhD[1,2] | Yan Luo MD, PhD[3] | Satoshi Funada MD, PhD[4] | Takeshi Hashimoto MD, PhD[5] | Kunitaka Matsuishi MD, PhD[6] | Toko Takamatsu MD, PhD[7] | Yasuo Yoshihara MD, PhD[8] | Yayoi Hiraoka MD[9] | Yasutaka Mizui MD[10] | Yu Hayasaka MD, PhD[1,11] | Nozomi Takeshima MD, PhD[1,12] | Haruko Fukushima MD[6] | Kohei Matsuda MD[6] | Takashi Hashimoto MD[6] | Toshi A. Furukawa MD, PhD[13]

[1]Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine/School of Public Health, Kyoto, Japan

[2]Ohashi Psychiatry Clinic, Takarazuka, Japan

[3]Center for Medical Education and Internationalization, Kyoto University Graduate School of Medicine, Kyoto, Japan

[4]Health Technology Assessment Unit, Department of Preventive Medicine and Public Health, Keio University School of Medicine, Tokyo, Japan

[5]Hashimoto Takeshi Psychiatry Clinic, Kobe, Japan

[6]Department of Psychiatry, Kobe City Medical Center General Hospital, Kobe, Japan

[7]Momofuku Psychiatry Clinic, Osaka, Japan

[8]Yoshihara Psychiatry Clinic, Nishinomiya, Japan

[9]Takaraduka Psychiatry Clinic, Takaraduka, Japan

[10]Flower Road Psychiatry Clinic, Takaraduka, Japan

[11]Otaka Psychiatry Clinic, Nagareyama, Japan

[12]Tsunagari Clinic, Fujisawa, Japan

[13]Office of Institutional Advancement and Communications, Kyoto University, Kyoto, Japan

Correspondence
Hissei Imai, MD, PhD, Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine/School of Public Health, Yoshida Konoe-cho, Sakyo-ku, Kyoto 606-8501 Japan.
Email: ihits@hotmail.com

Funding information
Japan Society for the Promotion of Science, Grant/Award Number: 21K15729; Mental Health Okamoto Memorial Foundation

Abstract

Background: Self-help programs without therapist involvement for obsessive–compulsive disorder (OCD) are promising, but the high dropout rate is a significant issue. Our software, which incorporates entertainment elements, showed a completion rate of over 80% in a pre–post comparison study, with superior effectiveness. This is the protocol for a study that aims to evaluate the efficacy and tolerability of a video-based mobile application for OCD treatment through a randomized controlled trial.

Methods: This study is designed as a randomized controlled trial with two parallel group comparison, with assessors blinded to group allocation. The study will include outpatients aged 18 years or older diagnosed with OCD. The intervention group will

receive a mobile-device-based intervention using an application grounded in cognitive behavioral therapy. The treatment period will be 8 weeks, during which 21 sessions will be conducted. Participants not allocated to the intervention group will be assigned to a waitlist control group for 8 weeks. The primary outcome for effectiveness will be the comparison of the Yale–Brown Obsessive Compulsive Scale. As the primary outcome for tolerability, participants in the intervention group who complete 80% or more of the sessions by the 8-week point will be defined as treatment completers, and the proportion of completers will be calculated. Assuming a 10% attrition rate, a total of 88 participants will be needed.

Results: Results will be presented according to the protocol.

Conclusions: If this study demonstrates that OCD can be improved through mobile-based self-help treatment without therapist involvement, it will become an important treatment option for patients.

KEYWORDS

adult, anxiety disorders, cognitive behavioral therapy, information science category, psychotherapy

INTRODUCTION

Obsessive–compulsive disorder (OCD) is a serious condition that imposes a significant burden on individuals, caregivers, and society. It is characterized by the presence of repetitive and persistent obsessions and compulsions, which consume the patient's time and lead to exhaustion.[1]

OCD is not rare and carries a substantial economic burden. A systematic review encompassing 42 studies reported a median 1-year prevalence of 1.0% (interquartile range: 0.6–2.0) for OCD, which is higher than that for schizophrenia and bipolar disorder and comparable to that for panic disorder.[2]

Given the seriousness of the condition and its prevalence, the annual cost associated with OCD is enormous. In the United States alone it has been estimated at $10.6 billion in one study and £5 billion in another.[2,3] Studies indicate that untreated OCD has a poor natural course, highlighting the importance of early intervention for the benefit of individuals, caregivers, and society.[4]

Pharmacotherapy and psychotherapy are effective in the treatment of OCD. Behavioral and cognitive therapies have been shown to be more effective than SSRIs, although many of the included studies combined these therapies with antidepressant treatment. The effect size of behavioral therapy and cognitive therapy was substantial, with a mean difference of −14.48 and −13.36 in the Yale–Brown Obsessive Compulsive Scale (Y-BOCS; score range 0–40) when compared to placebo.[5]

However, the journey to treatment initiation for OCD patients is often prolonged. Several studies have reported that it takes 7–12 years for OCD patients to seek treatment.[6–10] Some studies also indicate that the time to treatment is longer for OCD than for depression or panic disorder.[10] A review identified common barriers to help-seeking across studies, including embarrassment about symptoms or seeking help, uncertainty about where to seek help, and the perceived inconvenience of treatment.[11] The inconveniences included the time commitment and effort required for treatment, as well as challenges related to transportation and scheduling.[11]

One potential solution to these challenges is the use of digital devices. Digital devices may shorten the waiting time to receive appropriate treatment and reduce treatment-related costs.[12,13] In fact, a systematic review has shown that self-help programs without therapist involvement for OCD are effective.[14] This study includes 11 studies, of which seven were conducted by the same research team. The absence of studies from the Asian region, the high risk of bias in the individual studies included, and the substantial heterogeneity may have influenced the results. However, a significant issue was the high dropout rate. The dropout rate was 25.5% in the control group, while 39.7% of participants dropped out in the unguided treatment group. Existing treatments are often text-based, with few mechanisms to prevent dropout, such as gamification elements.[14] Previous studies have also demonstrated a high dropout rate in treatments without guidance. A systematic review of self-help interventions for patients with OCD, including 18 studies, reported that the mean (standard deviation) dropout rates for self-administered self-help and minimal-contact self-help interventions were 38.7% (32.47) and 16.68% (10.61), respectively.[15] Similarly, another systematic review of Internet-based cognitive behavioral therapy (CBT), comprising 17 studies, found that the mean (95% confidence interval) dropout rates for self-guided interventions and clinician-guided interventions were 51.3% (35.8–66.6) and 19.9% (12.9–29.4), respectively.[16] We have therefore developed a new movie-based mobile therapy for OCD (Figure 1). Our software, which incorporates entertainment elements, showed a completion rate of over 80% in a pre–post comparison study, with superior effectiveness.[17] However, the number of participants in the study was small, and no definitive conclusions can be drawn.

FIGURE 1 Screen shots of new movie-based mobile therapy for obsessive–compulsive disorder.

Therefore, this study aims to validate the efficacy and tolerability of a video-based mobile application for OCD treatment through a randomized controlled trial.

METHODS AND ANALYSIS

Study design

This study is designed as a randomized controlled trial with two parallel group comparison, with assessors blinded to group allocation. The study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[18]

Participants

The study will include outpatients aged 18 years or older diagnosed with OCD, who regularly use mobile devices in their daily lives. The diagnosis will be based on the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition (DSM-5)[1] using the *Structured Clinical Interview for DSM-5*, Research Version.[19] Patients who require imminent hospitalization, pose a risk of suicide or self-harm, have intellectual disabilities, have comorbid schizophrenia, or have previously undergone behavioral therapy or CBT will be excluded. Concomitant therapies, including pharmacotherapy, will be allowed.

The study will be conducted in a multicenter, secondary care, outpatient setting.

Intervention

The intervention group will receive a mobile-device-based intervention using an application grounded in CBT. The treatment period will be 8 weeks, during which 21 sessions will be conducted. Each session lasts between 5 and 30 min and is video-based, focusing on psychoeducation, monitoring, and exposure and response prevention (ERP). Homework will be assigned for each session, which can be completed using the in-app program. The homework for the initial sessions is self-monitoring. The purpose of self-monitoring is to objectively observe when compulsive behaviors occur, what fears are associated with them, and the intensity of the anxiety experienced. At the end of each session, participants will have the option to watch an adventure entertainment video. Although viewing is not mandatory, the video includes content designed to encourage and enhance motivation. Thse videos are pre-recorded and participants will access them at their convenience. Automated reminder emails will be sent at regular intervals throughout the 8-week period. The detailed structure of the sessions is shown in Table 1.

The intervention is self-help application, without involvement from the attending physician. Standardized reminder emails will be sent regularly via a separate platform automatically. Each text will be

TABLE 1 The detailed structure of the sessions.

Session	Contents
1	Goal setting
2–6	Psychoeducation and self-monitoring
7	Rationale of the treatment
8	Anxiety hierarchy
9, 10, 12, 14, 16, 18	Exposure and response prevention
11	Family accommodation
13	Motivation
15	Everyday tips
17, 19	Review of previous sessions
20	Relapse prevention
21	Finale

predetermined, standardized, and sent on a predetermined date. Only technical issues, such as software malfunctions, will be addressed; no questions regarding the treatment content or progress will be answered.

Comparison

Participants not allocated to the intervention group will be assigned to a waitlist control group for 8 weeks. During this period, they will receive the usual care, but will not undergo any psychotherapy that includes ERP.

Outcomes

The primary outcome for effectiveness will be the comparison of the Y-BOCS[20] score between the intervention and control groups. The Y-BOCS is a measure of OCD severity, consisting of 10 items (five related to obsessions and five related to compulsions) each rated on a scale from 0 to 4, with higher total scores indicating greater severity. The Japanese version of the Y-BOCS has been validated and shown to be reliable.[21] The Bang method will be used to assess the quality of blinding of the evaluators.[22] As the primary outcome for tolerability, participants in the intervention group who complete 80% or more of the sessions by the 8-week point will be defined as treatment completers, and the proportion of completers will be calculated. Participants who complete <50% of the sessions by the 8-week point will be defined as treatment dropouts.

Secondary outcomes will include self-reported assessments of OCD symptoms, response rate, remission rate, depressive symptoms, quality of life (QOL), and the attitude towards the application, evaluated both before the intervention and at the 8-week point. In addition, the number of sessions completed at the 8-week point will be descriptively evaluated in the intervention group as a measure of tolerability.

Self-reported OCD symptoms will be assessed using the Obsessive–Compulsive Inventory-Revised (OCI-R),[23] which consists of 18 items rated on a five-point scale from 0 to 4, with higher total scores indicating greater severity. The OCI-R measures distress related to common OCD symptoms. The Japanese version of the OCI-R has been validated and shown to be reliable.[24] Response is defined as a 30% reduction in the Y-BOCS score,[25] and remission is defined as a Y-BOCS score of 14 or less.[26]

Depressive symptoms will be assessed using the Patient Health Questionnaire (PHQ-9),[27] a self-report measure commonly used for screening mood and anxiety disorders. The PHQ-9 is based on the nine diagnostic criteria for major depressive disorder in the DSM-IV, with each item rated on a four-point scale, and higher scores indicating more severe depressive symptoms. The Japanese version of the PHQ-9 has been validated and shown to be reliable.[28]

QOL will be assessed using the five-level EQ-5D version (EQ-5D-5L),[29] a widely used self-report measure of health-related QOL developed by the EuroQol Research Foundation. It consists of five items, each rated on a five-point scale.[30]

The participants' attitudes towards the application will be assessed in the intervention group using the Scale To Assess Therapeutic Relationship (STAR).[31] We will assess participants' relationships with the application. The STAR is a measure used to assess the therapeutic relationship between healthcare providers and patients with mental disorders in community care settings. There are versions for both healthcare providers and patients; in this study, only the patient version will be used. It consists of 12 items, each rated on a five-point scale, with higher scores indicating a better therapeutic relationship. The Japanese version of the STAR has been validated and shown to be reliable.[32]

Sample size

Sample size calculations are based on a systematic review and meta-analysis of unguided OCD treatments, assuming an effect size of standard mean difference = −0.64 for the intervention.[14] With a significance level of 0.05 and a power of 80%, 40 participants per group are required. Assuming a 10% attrition rate, a total of 88 participants will be needed.

Randomization

Sequence generation and allocation concealment

Randomization will be conducted using the UMIN INDICE system, which is an Internet randomization and allocation service, employing a minimization method with the use of antidepressants and age (18–39 years, 40–59 years, or 60 years or more) as a stratification factor, and participants will be allocated to the intervention and control groups in a 1:1 ratio.[33] Allocation concealment will therefore be maintained.

Implementation

When the attending physician deems it appropriate and the patient expresses interest, the physician will report the case to an independent randomization center. A physician at the randomization center will then contact the patient by Internet conference system to confirm eligibility criteria. After explaining the study and obtaining informed consent from the patient, the Y-BOCS evaluation will be conducted. Additional baseline assessments, including self-reported measures (OCI-R, PHQ-9, EQ-5D-5L), as well as demographic information, such as gender, age, age of symptom onset, and use of antidepressants, will be collected online separately from the interview. After confirming the responses, online randomization will be performed to allocate participants to either the intervention or control group.

Blinding

Due to the nature of the intervention and the waiting list control, the treating psychiatrists and the patients cannot be blinded to the intervention.

At 4 and 8 weeks, the Y-BOCS evaluation will be conducted by a trained clinical psychologist who is blinded to the group allocation remotely by telephone. Secondary outcome measures will be assessed through online self-report questionnaires. We will ask the evaluator whether the subject belongs to the treatment group, the wait-list group, or if they are unsure so that the blinding of the assessor can be evaluated with Bang's index. Participants who complete all evaluations at the 8-week point will receive a 1000-yen Amazon gift card as a token of appreciation (Table 2; Figure 2).

TABLE 2 The schedule of enrolment and assessments.

	Study period		
	Enrolment and allocation	Post-allocation	Close-out
Timepoint	0	4 weeks	8 weeks
Enrolment			
Eligibility screen	X	—	—
Informed consent	X	—	—
Allocation	X	—	—
Assessments			
Objective measure – Y-BOCS	X	X	X
Subjective measures			
– OCI-R	X	—	X
– PHQ-9	X	—	X
– EQ-5D-5L	X	—	X
– STAR	—	—	X

Abbreviations: EQ-5D-5L, 5-level EQ-5D version; OCI-R, Obsessive–Compulsive Inventory-Revised; PHQ-9, Primary Health Questionnaire-9; STAR, Scale To Assess Therapeutic Relationship; Y-BOCS, Yale–Brown Obsessive Compulsive Scale.

Statistical methods

The analysis will be conducted by a statistician blinded to group allocation. Intention-to-treat analysis will be performed, regardless of dropout from the intervention. The primary effective outcome (Y-BOCS) measures will be analyzed using a linear mixed model for repeated measures (MMRM) for the full analysis set (FAS), defined as those with repeated-measures data. The MMRM model is considered appropriate under the assumption that missing data are missing at random. In the primary analysis for the effectiveness, the mixed-effects model will incorporate the allocated group (intervention or control), assessment time points (Weeks 4 and 8), the interaction term between the allocated group and assessment time point, and baseline covariates, including baseline age, duration of illness, and severity. These covariates were selected based on systematic reviews of previous studies, which identified age as a factor influencing the efficacy of CBT involving ERP,[34] and severity and duration of illness as predictors of OCD chronicity.[35] The assessment time points will be included as a categorical variable in the model, without any specific assumptions regarding changes over time. The variance–covariance matrix structure of the MMRM will be assumed to be unstructured for greater flexibility, but if convergence issues arise, simpler covariance structures, such as compound symmetry, will be considered. The difference in least square means between groups at Week 8, along with its 95% confidence interval and *p*-value, will be calculated using the MMRM. The significance level will be set at two-sided 5%. For the sensitivity analysis, the mean difference of Y-BOCS scores at Week 8 will be calculated for patients who have Y-BOCS data at Week 8, and a *t*-test will be used.

For the primary acceptability outcome, the proportions of treatment completers (those completing 80% or more of sessions by Week 8) and dropouts (those completing <50% of sessions by Week 8) in the intervention group will be calculated and descriptively compared with prior studies.

For secondary outcomes, differences in OCI-R, PHQ-9, and EQ-5D-5L scores at Week 8 will be analyzed using *t*-tests. Intention-to-treat analysis will be conducted regardless of dropout. Remission and response rates at Week 8, with missing values treated as non-responders, will be analyzed using the χ^2 test. The outcomes related to acceptability and therapeutic relationship with the app (STAR) will be descriptively presented.

We will conduct a sensitivity analysis, limited to participants who do not undergo any changes in their medication. A sensitivity analysis limited to completers will be conducted for remission and response.

DISCUSSION

This study aims to evaluate the effectiveness and tolerability of a mobile application for the treatment of OCD that does not involve a therapist. The study is a randomized controlled trial with evaluator

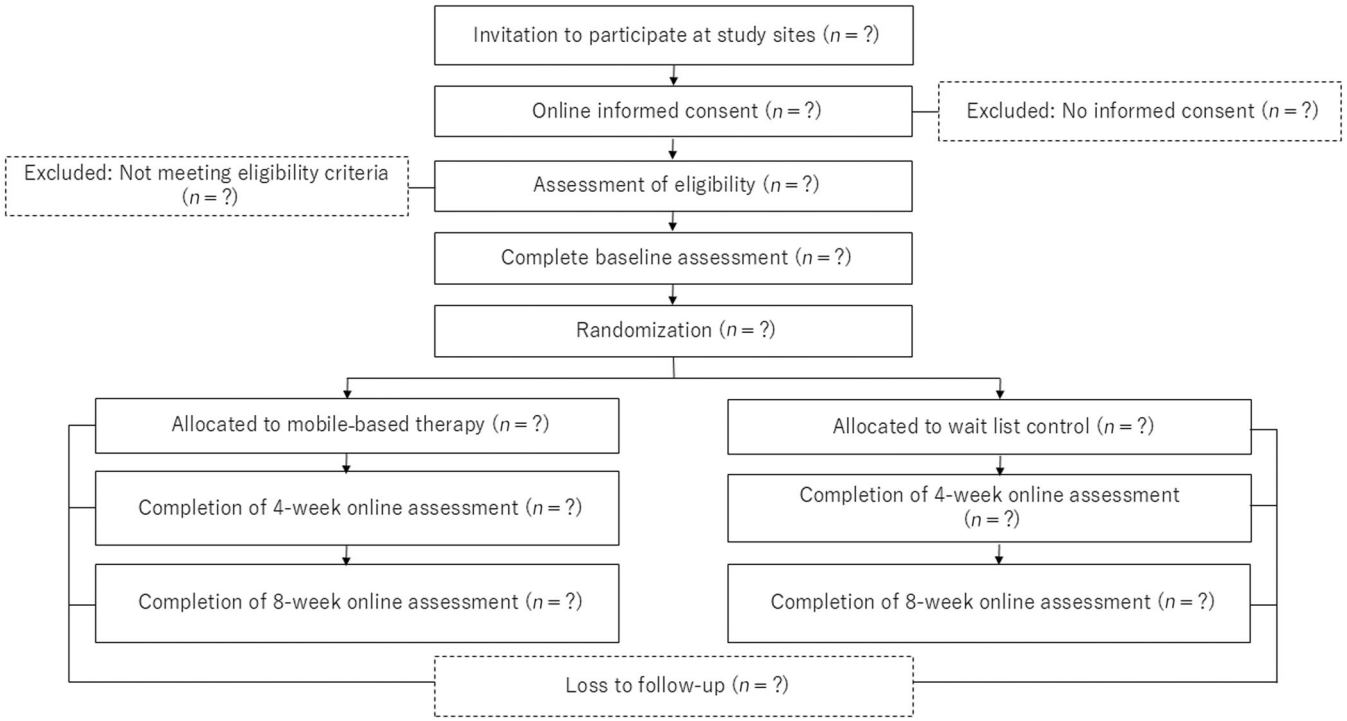

FIGURE 2 Flow diagram for study participants.

blinding, comparing two groups: an intervention group using the application and a control group on a waiting list.

Globally, there are only a few randomized controlled trials that have tested the effectiveness of OCD applications using information technology without therapist involvement (and so far none in Japan). However, these studies have shown high dropout rates and lacked strategies to prevent dropouts.[14] In this study, we will use an application that incorporates an adventure story to help maintain patient motivation. Preliminary studies have shown high completion rates with this approach.[17] This study will test whether the motivation-maintaining mechanism is acceptable in an automated treatment setting.

The outcomes of the study will include two measures of OCD symptoms, one measure of depressive mood, one measure of QOL, and one measure of the therapeutic relationship. In psychotherapy, the therapeutic relationship is a crucial factor.[36,37] However, to date, no studies have examined the therapeutic relationship in automated treatment using applications. This study will be the first to investigate how the therapeutic relationship with the application affects the treatment outcome.

Compared to previous studies, the method of patient recruitment also differs. In prior studies, patients were recruited through Internet forums, OCD-related Facebook groups and an Internet self-help group.[14] The diagnosis of OCD was based on self-report.[14] In the present study, however, OCD diagnoses were conducted in outpatient settings using structured interviews. This method allows for the recruitment of more accurately diagnosed OCD patients compared to previous approaches.

If this study demonstrates that OCD can be improved through automated treatment without therapist involvement, it will become an important treatment option for patients who have limited opportunities to receive face-to-face therapy.

DISCLOSURE STATEMENT

Hissei Imai received lecture fees from Takeda Pharmaceuticals, Otsuka Pharmaceutical, and VIATRIS. Kunitaka Matsuishi received lecture fees from Takeda Pharmaceuticals, Otsuka Pharmaceutical, and Sumitomo Pharma. Haruko Fukushima received lecture fees from Otsuka Pharmaceutical, Eisai Pharmaceuticals, and Meiji Seika Pharma. Toshi A. Furukawa reports personal fees from Boehringer-Ingelheim, Daiichi Sankyo, DT Axis, Micron, Shionogi, SONY, and UpToDate, and a grant from DT Axis and Shionogi, outside the submitted work. In addition, Toshi A. Furukawa has a patent 7448125 and a pending patent 2022-082495 and has licensed intellectual properties for Kokoro-app to Mitsubishi-Tanabe. The other authors have no competing interests to disclose.

AUTHOR CONTRIBUTION

Hissei Imai conceived of the study. Hissei Imai, Toshi A. Furukawa, Yan Luo, and Satoshi Funada initiated the study design. Yan Luo provided statistical expertise. Takeshi Hashimoto, Kunitaka Matsuishi, Toko Takamatsu, Yasuo Yoshihara, Yayoi Hiraoka, Yasutaka Mizui, Yu Hayasaka, Nozomi Takeshima, Haruko Fukushima, Kohei Matsuda, and Takashi Hashimoto helped with implementation. All authors

contributed to refinement of the study protocol and approved the final manuscript.

ACKNOWLEDGMENTS

This work was supported by Japanese Society for the Promotion of Science Grants-in-Aid for Scientific Research Grant Number 21K15729 and Mental Health Okamoto Memorial Foundation Research Grant. These funding sources had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

N/A

ETHICS APPROVAL STATEMENT

Approval was obtained from the Ethics Committee of the Japanese Association for Neuro-Psychiatric Clinics (2024-4-2).

PATIENT CONSENT STATEMENT

Written and verbal explanations will be provided to all participants, and informed consent will be obtained.

CLINICAL TRIAL REGISTRATION

The trial was registered with the UMIN Clinical Trials Registry (UMIN000056021).

ORCID

Hissei Imai http://orcid.org/0000-0003-3656-5188
Haruko Fukushima http://orcid.org/0000-0001-8616-8813

REFERENCES

1. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: Author; 2013.
2. Eaton WW, Martins SS, Nestadt G, Bienvenu OJ, Clarke D, Alexandre P. The burden of mental disorders. Epidemiol Rev. 2008;30:1–14.
3. Kochar N, Ip S, Vardanega V, Sireau NT, Fineberg NA. A cost-of-illness analysis of the economic burden of obsessive-compulsive disorder in the United Kingdom. Compr Psychiatry. 2023;127:152422.
4. Eisen JL, Pinto A, Mancebo MC, Dyck IR, Orlando ME, Rasmussen SA. A 2-year prospective follow-up study of the course of obsessive-compulsive disorder. J Clin Psychiatry. 2010;71:1033–9.
5. Skapinakis P, Caldwell DM, Hollingworth W, Bryden P, Fineberg NA, Salkovskis P, et al. Pharmacological and psychotherapeutic interventions for management of obsessive-compulsive disorder in adults: a systematic review and network meta-analysis. Lancet Psychiatry. 2016;3:730–9.
6. Vigne P, Fortes P, Dias RV, Laurito LD, Loureiro CP, de Menezes GB, et al. Duration of untreated illness in a cross-diagnostic sample of obsessive-compulsive disorder, panic disorder, and social anxiety disorder. CNS Spectr. 2019;24:526–32.
7. Albert U, Barbaro F, Bramante S, Rosso G, De Ronchi D, Maina G. Duration of untreated illness and response to SRI treatment in obsessive-compulsive disorder. Eur Psychiatry. 2019;58:19–26.
8. Poyraz CA, Turan Ş, Sağlam NGU, Batun GÇ, Yassa A, Duran A. Factors associated with the duration of untreated illness among patients with obsessive compulsive disorder. Compr Psychiatry. 2015;58:88–93.
9. Dell'Osso B, Benatti B, Grancini B, Vismara M, De Carlo V, Cirnigliaro G, et al. Investigating duration of illness and duration of untreated illness in obsessive compulsive disorder reveals patients remain at length pharmacologically untreated. Int J Psychiatry Clin Pract. 2019;23:311–3.
10. Altamura AC, Buoli M, Albano A, Dell'Osso B. Age at onset and latency to treatment (duration of untreated illness) in patients with mood and anxiety disorders: a naturalistic study. Int Clin Psychopharmacol. 2010;25:172–9.
11. García-Soriano G, Rufer M, Delsignore A, Weidt S. Factors associated with non-treatment or delayed treatment seeking in OCD sufferers: a review of the literature. Psychiatry Res. 2014;220:1–10.
12. Lind C, Boschen MJ, Morrissey S. Technological advances in psychotherapy: implications for the assessment and treatment of obsessive compulsive disorder. J Anxiety Disord. 2013;27:47–55.
13. Ferreri F, Bourla A, Peretti C-S, Segawa T, Jaafari N, Mouchabac S. How new technologies can improve prediction, assessment, and intervention in obsessive-compulsive disorder (e-OCD): review. JMIR Ment Health. 2019;6:e11643.
14. Imai H, Tajika A, Narita H, Yoshinaga N, Kimura K, Nakamura H, et al. Unguided computer-assisted self-help interventions without human contact in patients with obsessive-compulsive disorder: systematic review and meta-analysis. J Med Internet Res. 2022;24:e35940.
15. Pearcy CP, Anderson RA, Egan SJ, Rees CS. A systematic review and meta-analysis of self-help therapeutic interventions for obsessive-compulsive disorder: Is therapeutic contact key to overall improvement? J Behav Ther Exp Psychiatry. 2016;51:74–83.
16. Waks S, Moses K, Wootton BM. Acceptability of internet-delivered cognitive behavioural therapy for adults with symptoms of obsessive-compulsive disorder: A meta-analysis. Br J Clin Psychol. 2024;63:315–29.
17. Imai H, Furukawa TA. Unguided self-help movie- and mobile-based therapy for patients with obsessive–compulsive disorder: results of two pilot studies. PCN Rep. 2024;3:e70009.
18. Chan A-W, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586.
19. First M, Williams J, Karg R, Spitzer R. Structured clinical interview for DSM-5, Research Version. Arlington, VA: American Psychiatric Association; 2015.
20. Goodman WK. The Yale-Brown obsessive compulsive scale. I. Development, use, and reliability. Arch Gen Psychiatry. 1989;46(11):1006.
21. Nakajima T, Nakamura M, Taga C, Yamagami S, Kiriike N, Nagata T, et al. Reliability and validity of the Japanese version of the Yale-Brown obsessive-compulsive scale. Psychiatry Clin Neurosci. 1995;49:121–6.
22. Bang H, Ni L, Davis CE. Assessment of blinding in clinical trials. Controlled Clin Trials. 2004;25:143–56.
23. Huppert JD, Walther MR, Hajcak G, Yadin E, Foa EB, Simpson HB, et al. The OCI-R: validation of the subscales in a clinical sample. J Anxiety Disord. 2007;21:394–406.
24. Koike H, Tsuchiyagaito A, Hirano Y, Oshima F, Asano K, Sugiura Y, et al. Reliability and validity of the Japanese version of the Obsessive-Compulsive Inventory-Revised (OCI-R). Curr Psychol. 2020;39:89–95.
25. Tolin DF, Abramowitz JS, Diefenbach GJ. Defining response in clinical trials for obsessive-compulsive disorder: a signal detection analysis of the Yale-Brown obsessive compulsive scale. J Clin Psychiatry. 2005;66:1549–57.

26. Farris SG, McLean CP, Van Meter PE, Simpson HB, Foa EB. Treatment response, symptom remission, and wellness in obsessive-compulsive disorder. J Clin Psychiatry. 2013;74:685–90.
27. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16:606–13.
28. Muramatsu K, Miyaoka H, Kamijima K, Muramatsu Y, Tanaka Y, Hosaka M, et al. Performance of the Japanese version of the Patient Health Questionnaire-9 (J-PHQ-9) for depression in primary care. Gen Hosp Psychistry. 2018;52:64–9.
29. Golicki D, Młyńczak K. Measurement properties of the EQ-5D-Y: a systematic review. Value Health. 2022;25:1910–21.
30. Shiroiwa T, Ikeda S, Noto S, Igarashi A, Fukuda T, Saito S, et al. Comparison of value set based on DCE and/or TTO data: scoring for EQ-5D-5L health states in Japan. Value Health. 2016;19:648–54.
31. McGuire-SnieckuS R, McCabe R, Catty J, Hansson L, Priebe S. A new scale to assess the therapeutic relationship in community mental health care: STAR. Psychol Med. 2007;37:85–95.
32. Matsunaga A, Yamaguchi S, Sawada U, Shiozawa T, Fujii C. Psychometric properties of Scale to Assess the Therapeutic Relationship—JapaneseVersion (STAR-J). Front Psychiatry. 2019;10:575.
33. University hospital Medical Information Network (UMIN) Center. UMIN Internet data and information system for clinical and epidemiological research, Cloud version. Available from https://www.umin.ac.jp/indice/
34. Reid JE, Laws KR, Drummond L, Vismara M, Grancini B, Mpavaenda D, et al. Cognitive behavioural therapy with exposure and response prevention in the treatment of obsessive-compulsive disorder: A systematic review and meta-analysis of randomised controlled trials. Compr Psychiatry. 2021;106:152223.
35. van Oudheusden LJB, Eikelenboom M, van Megen HJGM, Visser HAD, Schruers K, Hendriks G-J, et al. Chronic obsessive–compulsive disorder: prognostic factors. Psychol Med. 2018;48:2213–22.
36. Nienhuis JB, Owen J, Valentine JC, Winkeljohn Black S, Halford TC, Parazak SE, et al. Therapeutic alliance, empathy, and genuineness in individual adult psychotherapy: a meta-analytic review. Psychother Res. 2018;28:593–605.
37. Martin DJ, Garske JP, Davis MK. Relation of the therapeutic alliance with outcome and other variables: a meta-analytic review. J Consult Clin Psychol. 2000;68:438–50.

How to cite this article: Imai H, Luo Y, Funada S, Hashimoto T, Matsuishi K, Takamatsu T, et al. Movie- and mobile-therapy without therapist involvment for patients with obsessive–compulsive disorder: protocol for a randomized controlled trial. Psychiatry Clin Neurosci Rep. 2025;4:e70065. https://doi.org/10.1002/pcn5.70065