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## Patients' acceptability and implementation outcomes of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia: a secondary analysis of a mixed-method randomized clinical trial

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Complete List of Authors:	<p>Yamada, Yuto; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Neuropsychiatry; Okayama University Hospital, Department of Neuropsychiatry  Fujiwara, Masaki; Okayama University Hospital, Department of Neuropsychiatry  Shimazu, Taichi; National Cancer Center, Division of Behavioral Sciences, Institute for Cancer Control  Etoh, Tsuyoshi; Shimane University Hospital, Department of Nursing  Kodama, Masafumi; Okayama Psychiatric Medical Center  So, Ryuhei ; Okayama Psychiatric Medical Center  Matsushita, Takanori; Zikei Hospital  Yoshimura, Yusaku; Zikei Hospital  Horii, Shigeo; Zikei Hospital  Fujimori, Maiko; National Cancer Center Institute for Cancer Control, Division of Supportive Care, Survivorship and Translational Research  Takahashi, Hirokazu ; National Cancer Center Institute for Cancer Control, Division of Screening Assessment and Management  Nakaya, Naoki; Tohoku University, Tohoku Medical Megabank Organization  Miyaji, Tempei; The University of Tokyo, Department of Clinical Trial Data Management, Graduate School of Medicine  Hinotsu, Shiro ; Sapporo Medical University, Department of Biostatistics and Data Management  Harada, Keita; Okayama University Hospital, Department of Gastroenterology  Okada, Hiroyuki; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Gastroenterology and Hepatology  Uchitomi , Yosuke; National Cancer Center Institute for Cancer Control, Group for Supportive Care and Survivorship Research  Yamada, Norihito; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Neuropsychiatry  Inagaki, Masatoshi; Shimane University, Department of Psychiatry, Faculty of Medicine</p>
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**Title**

Patients' acceptability and implementation outcomes of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia: a secondary analysis of a mixed-method randomized clinical trial

**Authors**

Yuto Yamada, MD<sup>1, 2</sup>, Masaki Fujiwara MD, PhD<sup>2\*</sup>, Taichi Shimazu, MD, PhD<sup>3</sup>, Tsuyoshi Etoh, MS<sup>4</sup>, Masafumi Kodama, MD, PhD<sup>5</sup>, Ryuhei So, MD, MPH<sup>5</sup>, Takanori Matsushita, MD<sup>6</sup>, Yusaku Yoshimura, MD, PhD<sup>6</sup>, Shigeo Horii, MD, PhD<sup>6</sup>, Maiko Fujimori, PhD<sup>7</sup>, Hirokazu Takahashi, MD, PhD<sup>8</sup>, Naoki Nakaya, PhD<sup>9</sup>, Tempei Miyaji, MSc<sup>10, 11</sup>, Shiro Hinotsu, MD, PhD<sup>12</sup>, Keita Harada, MD, PhD<sup>13</sup>, Hiroyuki Okada, MD, PhD<sup>14</sup>, Yosuke Uchitomi, MD, PhD<sup>15</sup>, Norihito Yamada, MD, PhD<sup>1</sup>, Masatoshi Inagaki, MD, PhD<sup>16\*</sup>

**Affiliations**

<sup>1</sup>Department of Neuropsychiatry, Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences, Okayama, Japan

<sup>2</sup>Department of Neuropsychiatry, Okayama University Hospital, Okayama, Japan

<sup>3</sup>Division of Behavioral Sciences, Institute for Cancer Control, National Cancer Center, Tokyo, Japan

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<sup>4</sup>Department of Nursing, Shimane University Hospital, Izumo, Japan

<sup>5</sup>Okayama Psychiatric Medical Center, Okayama, Japan

<sup>6</sup>Zikei Hospital, Okayama, Japan

<sup>7</sup>Division of Supportive Care, Survivorship and Translational Research, National Cancer Center

Institute for Cancer Control, Tokyo, Japan

<sup>8</sup>Division of Screening Assessment and Management, National Cancer Center Institute for Cancer

Control, Tokyo, Japan

<sup>9</sup>Tohoku Medical Megabank Organization, Tohoku University, Sendai, Japan

<sup>10</sup>Department of Clinical Trial Data Management, Graduate School of Medicine, The University of

Tokyo, Tokyo, Japan

<sup>11</sup>Behavioral Sciences and Survivorship Research Group, Center for Public Health Sciences, National

Cancer Center, Tokyo, Japan

<sup>12</sup>Department of Biostatistics and Data Management, Sapporo Medical University, Sapporo, Japan

<sup>13</sup>Department of Gastroenterology, Okayama University Hospital, Okayama, Japan

<sup>14</sup>Department of Gastroenterology and Hepatology, Okayama University Graduate School of

Medicine, Dentistry and Pharmaceutical Sciences, Okayama, Japan

<sup>15</sup>National Cancer Center Institute for Cancer Control, Group for Supportive Care and Survivorship

Research, Tokyo, Japan

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<sup>16</sup>Department of Psychiatry, Faculty of Medicine, Shimane University, Izumo, Japan

**\*Correspondence**

Masaki Fujiwara, M.D., Ph.D.

Department of Neuropsychiatry, Okayama University Hospital

2-5-1 Shikata-cho, Kita-ku, Okayama, Japan

Tel: +81-86-235-7242

E-mail: [mfujiwara@okayama-u.ac.jp](mailto:mfujiwara@okayama-u.ac.jp)

Masatoshi Inagaki, M.D., Ph.D.

Department of Psychiatry, Faculty of Medicine, Shimane University

89-1 Enya-cho, Izumo, Shimane 693-8501, Japan

Tel: +81-853-20-2262

E-mail: [minagaki@med.shimane-u.ac.jp](mailto:minagaki@med.shimane-u.ac.jp)

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## ABSTRACT (300 words)

### Objectives

We examined the efficacy of case management (CM) interventions to encourage participation in colorectal cancer screening for schizophrenia patients. To implement this intervention into routine clinical practice, this study aimed to clarify patients' acceptability of the intervention, helpful components of the intervention, and the reasons for participation or non-participation in cancer screening. Simultaneously, the study aimed to determine the acceptability, appropriateness, and feasibility of the intervention from the perspective of psychiatric care providers.

### Study design and setting

This study was a secondary qualitative analysis of a mixed-method randomized controlled trial that evaluated the efficacy of the CM approach to encourage participation in cancer screening for people with schizophrenia. Interviews were conducted with patients with schizophrenia who received the intervention and staff from two psychiatric hospitals in Japan who delivered the intervention.

### Participants

Of the 172 patients with schizophrenia who participated in the trial, 153 were included in the analysis. In addition, three out of six case managers were included in the study.



### **Data collection**

Responses obtained during interviews with patients were extracted. For the interviews with the providers, opinions obtained from verbatim transcripts were extracted and summarized.

### **Findings**

Most patients perceived that the intervention was acceptable. For the intervention component, in-person counseling with an explanation of colorectal cancer screening by psychiatric care providers was most frequently reported as helpful by patients for undergoing cancer screening. Psychiatric care providers evaluated the intervention as acceptable, appropriate, and easy to understand and administer. However, providing the intervention to all patients simultaneously was considered difficult with the current human resources.

### **Conclusions**

This qualitative study showed that the intervention was perceived as acceptable by patients and acceptable and appropriate by psychiatric care providers. The next step is to conduct further research to implement the intervention in routine clinical practice.

**Keywords**

Cancer screening, schizophrenia, case management, patient navigation, mixed-method randomized controlled trial

**Trial registration**

UMIN000036017

**Strengths and limitations of the study**

- The efficacy of the case management approach to encourage participation in colorectal cancer screening for patients with schizophrenia was examined in our randomized controlled trial.
- This study clarified the acceptability and helpful components of the intervention from the patients' perspective and implementation outcomes (acceptability, appropriateness, and feasibility) from the providers' perspective.
- The findings of the present qualitative survey are valuable for implementing the intervention into routine clinical practice.
- Acceptability from the patients' perspective may be overestimated because we only examined the opinions of patients who consented to the randomized controlled trial for cancer screening encouragement.

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- We did not investigate psychiatric hospitals of all sizes/regions, which limits the generalizability of the present results.

For peer review only

## 1. BACKGROUND

Cancer is a leading cause of death among people with schizophrenia, and cancer mortality in those with schizophrenia is greater than that in the general population.[1, 2] Delayed cancer detection is one factor that contributes to the high cancer mortality rates in this population.[3,4] Therefore, there is a crucial need to encourage guideline-recommended screening in patients with schizophrenia.[5]

A previous study showed disparities in cancer screening among people with schizophrenia.[6, 7] Moreover, such disparities in cancer screening among people with a mental illness have persisted or become even wider.[8, 9] Therefore, we developed a case management (CM) approach to encourage participation in cancer screening, with a particular focus on colorectal cancer screening using a fecal occult blood test (FOBT), for patients with schizophrenia in psychiatric outpatient clinics.[10]

The efficacy of this intervention has been confirmed by a randomized controlled trial (RCT).[11] For the next step, it is necessary to confirm the effectiveness of this intervention in routine clinical settings. However, to implement a new intervention in routine clinical practice, it is valuable to determine patients' acceptability of the intervention and identify components of the intervention that patients perceive as helpful. This is because the intervention is complex and includes personal education and navigation for cancer screening. Furthermore, it is necessary to examine implementation outcomes, such as acceptability, appropriateness, and feasibility,[12] as

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7 perceived by psychiatric care providers.  
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10 During this trial, we conducted a pre-planned qualitative study to determine the information  
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12 needed to carry out future implementation research. In this qualitative study, we first aimed to evaluate  
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14 patients' acceptability of the intervention, identify helpful components of the intervention, and explore  
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16 the reasons for participation or non-participation in cancer screening. Second, we examined the  
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18 acceptability, appropriateness, and feasibility of the intervention as assessed by psychiatric care  
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20 providers.  
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## 29 **2. METHODS**

### 30 31 **2.1 Study design and participants**

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33 This study was a secondary analysis of a mixed-method RCT that evaluated the efficacy of the case  
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35 management approach to encourage participation in cancer screening for people with schizophrenia.  
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38 In this RCT, we interviewed study participants and psychiatric care providers who administered the  
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40 intervention. All participants provided written informed consent prior to enrolment. This study is  
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42 registered in the UMIN Clinical Trials Registry (UMIN000036017). The protocol of the trial, details  
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44 of the intervention, and main trial findings were reported elsewhere.[10, 11] Therefore, the method of  
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46 the trial is described briefly.  
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56 We recruited patients from two psychiatric outpatient clinics in Okayama City in Japan: the  
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58 Okayama Psychiatric Medical Center (252 beds and approximately 250 outpatient visits per day) and  
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6 Zikei Hospital (570 beds and approximately 160 outpatient visits per day). Eligible participants were  
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9 aged  $\geq 40$  years in the 2019 fiscal year; had visited the recruitment sites as their primary psychiatric  
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12 outpatient service; and were outpatients diagnosed by their current primary psychiatrist with  
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15 schizophrenia or schizoaffective disorder, according to the Diagnostic and Statistical Manual of  
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18 Mental Disorders, Fifth Edition.[13] Key exclusion criteria were patients with a history of colorectal  
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21 cancer; those living in an institution where residents were supported in receiving cancer screening;  
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24 and patients judged to be at risk of symptom worsening by participating in the study.  
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28 Patients were randomly assigned to receive usual intervention, which included municipal  
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30 public education (treatment as usual: TAU group), or an intervention to encourage participation in  
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33 cancer screening using CM plus TAU (CM plus TAU group).  
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## 39 **2.2 Cancer screening program provided by the municipality**

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42 In Japan, screenings for colorectal, gastric, lung, breast, and cervical cancer provided by local  
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45 governments are available with a low co-payment. In this study, we recommended colorectal cancer  
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48 screening using the FOBT for individuals aged 40 years and older. The cancer screening program of  
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51 Okayama City does not mail the FOBT kit in advance. Instead, individuals select a clinic offering  
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54 cancer screening and make an appointment to visit the clinic to receive the kit. Although individuals  
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57 with a low household income can receive free screening, eligible individuals must apply for a coupon  
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6 in advance at the municipal office.  
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9           The Okayama municipal government distributes a leaflet and detailed brochure encouraging  
10 participation in the above cancer screening program to all households in the city once a year.  
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### 18 **2.3 Case management intervention to encourage participation in cancer screening**

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21 A case manager (nurse or psychiatric social worker) provided three counseling sessions to the study  
22 participants allocated to the CM plus TAU group.  
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27           The first session, which was conducted in person, comprised the following components: a)  
28 education on the importance and content of colorectal cancer screening, using a pamphlet, b)  
29 assistance in making decisions and an appointment for colorectal cancer screening, and c) assistance  
30 in obtaining a coupon for free screening, if necessary. Other cancer screening was also briefly  
31 mentioned using the pamphlet. Education on cancer screening using the pamphlet did not take the  
32 approach whereby the seriousness or severity of cancer was emphasized.  
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45           After the first in-person session, a case manager provided at least two follow-up in-person  
46 or telephone counseling sessions to remind or support the patient's participation in cancer screening.  
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51 The follow-up session could be skipped if the subject was judged to be able to receive cancer screening  
52 without the follow-up sessions.  
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57           This intervention was standardized in the form of a manual. Psychiatric nurses or social  
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6 workers who had already worked at the study sites administered the intervention as case managers,  
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9 according to the procedures described in the manual.  
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## 15 **2.4 Follow-up interview conducted after the end of the intervention period**

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18 After the end of the municipal cancer screening period, qualitative follow-up interviews were  
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21 conducted with both case managers and study participants between January 2020 and March 2020.  
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### 27 **2.4.1 Interviews with patients**

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30 In a structured interview, the case manager asked the CM plus TAU group participants about “patients’  
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33 acceptability of the intervention,” “helpful components of the intervention,” and “reasons for  
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36 participation or non-participation in cancer screening.”  
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39 *For patients’ acceptability of the intervention*, patients were asked about “affective attitude,”  
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42 which is one of the components of the theoretical framework of acceptability.[14] This theoretical  
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45 framework was developed according to the overview of systematic reviews focusing on patients’  
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48 acceptability of healthcare interventions.[14] Patients were asked, “how do you feel about this  
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51 recommendation for cancer screening?”  
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54 *For helpful components of the intervention*, patients were asked to describe the components  
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57 of the intervention that they perceived as helpful. The interviewer categorized patients’ open-ended  
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6 responses into the following components of the intervention: assignment of a case manager;  
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9 explanation of colorectal cancer screening; explanation of the coupon for free screening; planning a  
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12 schedule for the cancer screening; and follow-up contact at a later date. Patients were asked, “what  
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15 was helpful in this intervention?”  
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18 For reasons for participation or non-participation in cancer screening, patients were asked  
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21 to describe their reasons for participation or non-participation with an open-ended question. The  
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24 interviewers categorized patients’ responses into predetermined options, which were based on a  
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27 Japanese public opinion survey on cancer control,[15] and were classified into the following categories  
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30 based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits;  
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33 perceived barriers; cue to action; and self-efficacy.[16] Patients were asked, “what were your reasons  
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36 for participating or not participating in colorectal cancer screening?”  
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#### 43 **2.4.2 Interviews with providers**

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45 A group interview was conducted with providers to assess the implementation outcomes of the  
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48 intervention. Proctor et al. proposed the Implementation Outcomes Framework,[17] which  
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51 conceptualizes the variables of interest in implementation evaluation. Among the implementation  
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54 outcomes included in this framework, we investigated “acceptability,” “appropriateness,” and  
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57 “feasibility,” which were all measurable factors in this study.  
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*Acceptability* is defined as the perception among providers that an intervention is agreeable, palatable, or satisfactory.[12] For “acceptability,” providers were asked, “what do you think about this intervention in terms of whether it is an agreeable, palatable, or satisfactory intervention?”

*Appropriateness* is defined as the perceived fit, relevance, or compatibility of the intervention for providers.[12] In this study, providers were asked, “did this intervention meet the objective of improving cancer screening uptake among people with schizophrenia?” and “were the components of the intervention fit for purpose to make the intervention effective?”

*Feasibility* is defined as the extent to which an intervention can be successfully used or carried out within a given setting.[12] In this study, providers were asked, “would this intervention be feasible to implement in a routine psychiatric outpatient setting?”

Two case managers who administered the intervention and a psychiatrist who was involved in the recruitment of the subjects participated in this study. One researcher (M.F1., a psychiatrist with 14 years of clinical experience) acted as the interviewer and facilitated discussions on the “acceptability,” “appropriateness,” and “feasibility” of the intervention.[11] The interview was recorded, and a verbatim transcript was produced.

## 2.5 Data analysis

For the analysis of patient responses, those whose self-reports of receiving colorectal cancer screening did not match the municipal records of the screening were excluded from the analysis to improve the

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6 validity of the results. For “patients’ acceptability of the intervention,” the open-ended responses were  
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9 coded following a discussion between two researchers (Y.Y., a psychiatrist with 6 years of clinical  
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12 experience, and T.E., a nurse with more than 10 years of clinical experience). For “helpful components  
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15 of the intervention,” “reasons for participation in cancer screening,” and “reasons for non-participation  
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18 in cancer screening,” responses obtained from the interviews were categorized into predetermined  
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21 options by the interviewers. Answers that did not fit into the predetermined options were coded by the  
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24 same researchers. Responses to “patients’ acceptability of the intervention” and “helpful components  
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27 of the intervention” were stratified according to whether patients had received cancer screening.  
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31 For the data obtained from the interviews with providers, the researcher extracted and  
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33 summarized the opinions obtained from the verbatim transcripts and asked the interviewees to revise  
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36 and confirm the summarized descriptions.  
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## 42 **2.6 Patient and public involvement statement**

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45 Patients were not directly involved in the development of the research questions and interventions or  
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48 in the design of the planned study. We obtained patients’ feedback regarding the intervention in this  
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51 study. The results of the study will be published on our facilities’ and funder’s website.  
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## 57 **3. RESULTS**

### 3.1 Patient enrolment and baseline characteristics

Between June 3, 2019, and September 9, 2019, 172 eligible participants were randomly assigned to either the CM plus TAU group (n = 86) or the TAU group (n = 86). Eighty participants in the CM plus TAU group (94.1%) and 83 participants in the TAU group (97.6%) took part in the follow-up interview. Of these, self-reports on whether they had received colorectal cancer screening were consistent with the results of the inquiry by Okayama City in 78 participants in the CM plus TAU group and 75 participants in the TAU group. There were inconsistencies between the self-reported results and the city's records for two participants in the CM plus TAU group and eight participants in the TAU group. The background information of the included 153 participants is shown in Table 1. Thirty-nine participants (50.0%) in the CM plus TAU group and one participant (10.0%) in the TAU group received cancer screening. Of these, seven participants in the CM plus TAU group and one in the TAU group required detailed examinations, such as colonoscopy, and all of these participants reported that they had undergone the prescribed detailed examination.

**Table 1. Patient characteristics**

	Case management intervention plus treatment as usual (N = 78)	Treatment as usual (N = 75)	Total (N = 153)
<b>Age, years</b>			
Median (range)	52 (39, 74)	54 (39, 80)	53 (39, 80)
<b>Sex</b>			
Women	37 (47.4%)	35 (46.7%)	72 (47.1%)
<b>Educational level*</b>			
≤ Junior high school	18 (23.1%)	15 (20.0%)	31 (20.3%)
> Junior high school but ≤ high school	36 (46.2%)	38 (50.7%)	74 (48.4%)
> High school but ≤ junior/vocational college	8 (10.3%)	9 (12.0%)	17 (11.1%)
≥ University or college	16 (20.5%)	13 (17.3%)	29 (19.0%)
<b>Marital status*</b>			
Married	9 (11.5%)	8 (10.7%)	17 (11.1%)
<b>Living alone*</b>			
Yes	39 (50.0%)	36 (48.0%)	75 (49.0%)
<b>Current outpatient for physical illness*</b>			
Yes	38 (48.7%)	35 (46.7%)	73 (47.7%)
<b>History of receiving colorectal cancer screening*</b>			
Yes	35 (44.9%)	30 (40.0%)	65 (42.5%)
No	43 (55.1%)	44 (58.7%)	87 (56.9%)
Unknown	0 (0%)	1 (1.3%)	1 (0.7%)
<b>mGAF score</b>			
Mean (SD)	49.6 (15.7)	50.9 (14.8)	50.2 (15.2)
Range	15, 85	25, 85	15, 85
<b>Participation in colorectal cancer screening</b>			
Received colorectal cancer screening	39 (50.0%)	10 (13.3%)	49 (32.0)
Needed a detailed examination*	7 (17.9%)	1 (10.0%)	8 (16.3%)
Received a detailed examination*	7 (100%)	1 (100%)	8 (100%)
Results of detailed examination*			
A polyp was detected and resected	3 (42.9%)	0 (0%)	3 (37.5%)
Haemorrhoid	1 (14.3%)	0 (0%)	1 (12.5%)
Enteritis	1 (14.3%)	0 (0%)	1 (12.5%)
No abnormal findings	2 (28.6%)	1 (0%)	3 (37.5%)

\*Self-reported.

Abbreviations: mGAF, modified global assessment of functioning; SD, standard deviation.

### 3.2 Patients' acceptability and helpful components of the intervention

Table 2 shows the responses obtained from patients regarding their impressions of the intervention.

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6 Of the 78 patients in the CM plus TAU group, 56 responded, of whom 30 received colorectal cancer  
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9 screening and 26 did not.  
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For peer review only

**Table 2. Patients' acceptability of the intervention\***

	Patients of CM plus TAU group who responded	
	Uptake of colorectal cancer screening	
	Yes (N = 30)	No (N = 26)
I was satisfied with the encouragement.	29	14
It was very good.	14	4
It was a good opportunity to receive cancer screening.	9	0
The explanations of cancer screening and the screening procedure were helpful.	3	4
I am glad that the polyp was treated quickly.	2	0
I would like this recommendation to be continued.	1	0
I felt it was important to have cancer screening.	1	6
It was not uncomfortable to be encouraged.	-†	1
I felt I did not need to undergo the screening right now.	-†	9
I felt it was bothersome.	1	1
I felt suspicious when they said "research."	-†	1

\*Multiple answers allowed. Patients were asked to provide open-ended responses.

†No responses on this content were obtained. Patients were not asked their opinion on this content in a close-ended question.

Abbreviations: CM, case management; TAU, treatment as usual.

Of the 39 patients in the CM plus TAU group who received colorectal cancer screening, 30 (76.9%) responded. Of the 39 patients in CM plus UI group who did not receive screening, 26 (66.7%) responded.

One patient provided multiple responses, stating that "the explanation of cancer screening and the screening procedure were helpful" and "I would like this recommendation to be continued."

Of the 30 patients who underwent colorectal cancer screening, 29 reported that they were satisfied with the encouragement. Specifically, the following comments were made by participants:

*"It was very good, please continue next year." ID 111*

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*“I am glad that a polyp was found and treated quickly.” ID 136*

Of the 26 patients who did not undergo cancer screening, 14 said they were satisfied with the encouragement. In addition, one patient voluntarily stated that they did not consider it uncomfortable to be encouraged. However, of the patients who did not undergo cancer screening, nine responded that they felt they did not need to undergo screening at the time. Specifically, the following comments were obtained:

*“It’s not necessary for me, so it doesn’t matter if you explain it to me.” ID 55*

Table 3 shows the responses from patients regarding the components of the intervention which were considered helpful. Among the patients in the CM plus TAU group who underwent cancer screening, the most common response was “explanation of colorectal cancer screening,” which was deemed helpful by 31 (81.6%) patients. This was followed by “assignment of a case manager” and “explanation of the coupon for free screening,” which were considered helpful by 19 (50.0%) and 17 (47.4%) patients, respectively.



**Table 3. Helpful components of the intervention\***

	Patients of the CM plus TAU group who responded (N = 68)			
	Uptake of colorectal cancer screening			
	Yes (N = 38)		No (N = 30)	
	N	%	N	%
Assignment of a case manager	19	50.0	8	26.7
Explanation of colorectal cancer screening	31	81.6	17	56.7
Explanation of the coupon for free screening	17	47.4	10	33.3
Planning a schedule for the cancer screening	4	13.2	2	6.7
Follow-up contact at a later date	15	39.5	5	16.7
No helpful points	5	10.5	8	23.3

\*Multiple answers allowed.

Abbreviations: CM, case management; TAU, treatment as usual.

Of the 39 patients who received colorectal cancer screening in the CM plus TAU group, 38 (97.4%) responded. Of the 39 patients who did not receive colorectal cancer screening in the CM plus UI group, 30 (76.9%) responded.

### 3.3 Reasons for participation or non-participation in cancer screening

Table 4 shows the responses obtained from patients regarding their reasons for undergoing colorectal cancer screening. The most common response was “because it was encouraged in this study,” which was the response of 22 (56.4%) patients. The second most common reason was “because I want to prevent cancer/detect cancer early,” which was the response of 16 patients (41.0%). Seven patients (17.9%) answered “because I am afraid of cancer.”

**Table 4. Reasons for participation in cancer screening\***

Categories	Patients' responses	Patients in CM plus TAU group who received cancer screening (N = 39)	
		N	%
Cue to action	Because it was encouraged in this study.	22	56.4
	Because it was encouraged by the primary psychiatrist.	7	17.9
	Because it was encouraged by my family physician.	1	2.6
	Because it was encouraged by my family.	0	0
	Because I received an invitation from the municipality.	1	2.6
	Because I had an upset stomach.	3	7.7
Perceived susceptibility	Because I was afraid of cancer.	7	17.9
	Because I had a family member with cancer.	4	10.3
	Because I had a friend with cancer.	1	2.6
Perceived benefit	Because I had other physical illnesses.	3	7.7
	Because I want to prevent cancer/detect cancer early.	16	41.0
Self-efficacy	Because I thought I could receive it.	5	12.8
Perceived barriers	Because it was not expensive.	15	38.5
	Because I found a clinic that was easy to visit.	6	15.4
Other	Because I receive cancer screening every year or sometimes.	14	35.9

\*Multiple answers allowed.

Reasons for participation in cancer screening were classified by researchers into the following categories based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.

Abbreviations: CM, case management; TAU, treatment as usual.

Table 5 shows the responses of patients regarding the reasons for not receiving cancer screening. The most common reason for not receiving cancer screening was “because it was bothersome,” given by 13 (33.3%) patients. Other common reasons were “I will visit a hospital when necessary” and “lack of knowledge about screening,” which were given by seven (17.9%) and five

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6 (12.8%) patients, respectively. For “lack of knowledge about cancer screening,” patients made the  
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9 following comments:

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12 *“I didn’t receive it because I have good bowel movements.” ID 67*

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15 *“I didn’t receive it because I had already had the screening before, and I thought I didn’t*  
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18 *need to take it again.” ID 160*

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21 Four patients (10.3%) provided the reason, “failure to receive cancer screening” and made the  
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24 following comments:

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27 *“I misunderstood the period during which the screening was conducted.” ID 75*

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30 *“I was going to see the doctor, but I forgot my coupon for free screening.” ID 4*  
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**Table 5. Reasons for non-participation in cancer screening\***

Categories	Patients' responses	Patients in the CM plus TAU group who did not receive cancer screening (N = 39)	
		N	%
Perceived barriers	Because it was bothersome.	13	33.3
	Because I did not feel the necessity to receive it every year.	5	12.8
	Because there was no time.	1	2.6
	Because it was a financial burden.	1	2.6
	Because I had anxiety about having tests and being diagnosed with cancer.	1	2.6
	Because of obstacles to transport.	0	0
Perceived severity	Because I will visit a hospital when necessary.	7	17.9
perceived susceptibility	Because I still have a long way to go before I get cancer.	1	2.6
Lack of knowledge	Because of the lack of knowledge about cancer screening.	5	5.1
Self-efficacy	Because I didn't feel like I could receive it.	0	0
Other	No particular reason.	1	2.6
<b>Content of free description</b>			
Perceived barriers	Because of failure to receive cancer screening.	4	10.3
	Because of psychiatric symptoms.	4	10.3
Perceived severity	Because of the belief that cancer does not need to be detected/treated early.	1	2.6
Other	Because I recently had a colonoscopy.	2	5.1
	Because I was suspicious of this research.	1	2.6

\*Multiple answers allowed.

Reasons for non-participation in cancer screening were classified by researchers into the following categories based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.

Abbreviations: CM, case management; TAU, treatment as usual.

### **3.4 Acceptability, appropriateness, and feasibility of the intervention from the providers' perspective**

The group interviews were conducted with three of the six providers who were involved in the intervention. The providers' backgrounds were a nurse with 20 years of clinical experience, a psychiatric social worker with 25 years of clinical experience and a psychiatrist with 11 years of clinical experience. The implementation outcomes of "acceptability," "appropriateness," and "feasibility" as assessed by the providers are summarized in Table 6.

**Table 6. Acceptability, appropriateness, and feasibility of the intervention from the providers' perspective**

Acceptability
<ul style="list-style-type: none"> <li>It is an acceptable intervention for psychiatric clinics to provide encouragement.</li> </ul>
Appropriateness
<ul style="list-style-type: none"> <li>Maintaining patients' physical health is one of the roles of psychiatric clinics.</li> <li>This intervention, which provides explanations and support tailored to each patient, is suited to the aim of enabling people with severe mental illness to have access to cancer screening.</li> <li>It is worthwhile to encourage and explain cancer screening in person, rather than only providing materials to encourage screening.</li> <li>It is important to explain to patients about the coupon for free screening. Some patients decided to receive screening after discovering it was available for free or at a low cost.</li> <li>Most patients were able to make an appointment with the hospital to receive cancer screening by themselves; thus, this intervention was appropriate.</li> <li>It is essential that the case manager and the patient choose which hospital to receive cancer screening together.</li> <li>Few patients changed their intentions of receiving/not-receiving cancer screening during the follow-up session. Therefore, follow-up sessions may not be necessary for all patients.</li> </ul>
Feasibility
<ul style="list-style-type: none"> <li>The intervention does not require time-consuming training sessions. Once explained, it is possible to administer the intervention in accordance with the procedures.</li> <li>The intervention procedure could be conducted in routine clinical practice.</li> <li>The intervention could be administered quickly for patients who have a family physician or a history of receiving cancer screening. As the number of those who have undergone cancer screening increases, the burden on case managers will reduce.</li> <li>It is difficult to encourage all patients eligible for colorectal cancer screening simultaneously because of limited resources. The impact of the COVID-19 epidemic introduced further difficulties.</li> <li>It is difficult to conduct follow-up sessions with the same staff member.</li> </ul>

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Regarding “acceptability,” the following comments were made:

*“There are many patients who think they should receive cancer screening but do not because they did not know much about cancer screening. It is an acceptable intervention for psychiatric clinics to provide encouragement that is tailored to the patient’s functional capabilities.” Psychiatric social worker, 25 years of clinical experience*

Regarding “appropriateness,” the following comments were made:

*“Maintaining patients’ physical health is one of the roles of psychiatric clinics.”*

*Psychiatrist, 11 years of clinical experience*

*“It is worthwhile to encourage and explain screening in person. Many patients may not receive screening if they are only given materials to encourage screening.” Nurse, 20 years of clinical experience*

*“It is important to explain about the coupon for free screening. Some patients decided to receive screening after realizing that it was available for free or at a low cost.”*

*Nurse, 20 years of clinical experience*

*“Many patients were able to go through the process on their own after receiving the explanation. It is an appropriate intervention.” Psychiatric social worker, 25 years of clinical experience*

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7 *“During the follow-up sessions, few patients changed their intentions of receiving/not-*  
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9 *receiving cancer screening or required additional support. Follow-up sessions may not*  
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11 *be necessary for all patients.” Psychiatric social worker, 25 years of clinical*  
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13 *experience*  
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18 In terms of “feasibility,” the following comments were made:  
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21 *“This intervention will take some getting used to but will not require time-consuming*  
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23 *training sessions. Once explained, it is possible to carry out the intervention in*  
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25 *accordance with the procedures.” Psychiatric social worker, 25 years of clinical*  
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27 *experience*  
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33 *“This intervention could be administered quickly for patients who have a history of*  
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35 *undergoing cancer screening. As the number of those who have undergone cancer*  
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37 *screening increases, the burden on case managers will be reduced.” Psychiatric social*  
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39 *worker, 25 years of clinical experience*  
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45 *“It is difficult to encourage all eligible patients for colorectal cancer screening at once*  
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47 *in terms of human resources. The impact of the COVID-19 epidemic made it even more*  
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49 *difficult.” Nurse, 20 years of clinical experience*  
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#### 54 55 56 57 **4. DISCUSSION** 58 59 60

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6 In this study, the CM intervention was evaluated as acceptable by patients. In-person counseling with  
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9 an explanation of cancer screening by psychiatric care providers was the most common reason for  
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12 receiving cancer screening. From the providers' perspective, the intervention delivered in a psychiatric  
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15 outpatient setting was perceived as "acceptable" and "appropriate." As was intended when the  
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18 intervention was developed, the intervention was simple for providers to understand and administer.  
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21 However, it was difficult to provide the intervention to all patients simultaneously, which presents a  
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24 challenge for its implementation in routine clinical practice. The results of this study may help  
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27 implement the CM intervention to encourage participation in colorectal cancer screening in clinical  
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30 practice.  
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#### 36 **4.1 Patients' acceptability and helpful components of the intervention**

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39 From the patients' perspective, evaluations of the intervention were mostly positive, which suggested  
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42 that there is patient demand for this intervention. In addition, few patients, including those who did  
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45 not receive colorectal cancer screening, reported any discomfort or anxiety about receiving the  
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48 intervention. This suggests that this intervention method is acceptable to most patients.  
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51 Regarding the components of the intervention that were considered helpful, most patients  
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54 reported that the explanation of the colorectal cancer screening process was helpful. Patients with  
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57 schizophrenia have barriers to accessing and understanding information about cancer screening.[18,  
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7 19] Moreover, many patients may not have been aware of the information distributed by the  
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9 municipality (i.e., the leaflet and brochure) or understood the procedure to receive colorectal cancer  
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11 screening. The present findings suggest that providing direct and individualized explanations is  
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13 effective in addressing these barriers.  
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#### 21 **4.2 Reasons for participation or non-participation in cancer screening**

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24 The largest proportion of patients stated that being encouraged in this study was the reason for  
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26 receiving cancer screening. This suggests that the CM intervention acted as an effective cue to undergo  
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28 cancer screening. This is consistent with a previous finding that physicians' recommendation of  
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30 screening is the strongest predictor of patients receiving cancer screening in those with psychiatric  
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32 disorders.[20] Furthermore, as other reasons for receiving screening, numerous patients highlighted  
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34 the desire for prevention/early detection of cancer and the low cost of cancer screening. This suggests  
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36 that the intervention was able to address the perceived benefits and barriers of patients with  
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38 schizophrenia. Few patients responded that fear of cancer was the reason for undergoing colorectal  
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40 cancer screening. This may be because the intervention did not emphasize the seriousness or severity  
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42 of cancer. In addition, a significant number of patients answered that they underwent cancer screening  
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44 because they had done so every year. Therefore, a simple intervention may be sufficient for such  
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46 patients. It is essential to encourage patients to undergo consistent colorectal cancer screening every  
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10 In a public opinion survey of the general population in Japan, the most common reason for  
11 not receiving cancer screening is “lack of time.”[16] However, few patients who participated in the  
12 present study cited lack of time or financial burden as reasons for not receiving cancer screening. In  
13 our study participants, the most common reason for not undergoing colorectal cancer screening was  
14 that it was bothersome, although the reasons why patients find cancer screening bothersome were not  
15 clarified in our survey. In addition, several patients could not fully appreciate the significance of  
16 screening or could not complete the procedure even after receiving the intervention. To overcome  
17 barriers to colorectal cancer screening in these patients, implementing system-level measures to enable  
18 the distribution of FOBT kits or conducting cancer screening at psychiatric hospitals may be effective.  
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#### 38 **4.3 Acceptability, appropriateness, and feasibility of the intervention from the providers’** 39 40 **perspective** 41

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44 The providers who provided the intervention evaluated it as an “acceptable” approach to encourage  
45 participation in cancer screening at the psychiatric outpatient clinic. Supporting the physical health of  
46 patients with mental illness was considered an important role of psychiatric outpatient clinics, and thus  
47 awareness of this issue should be raised within clinics when implementing the intervention.  
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56 It was also perceived as “appropriate” to provide patients with tailored navigation on cancer  
57 screening procedures. The CM intervention was considered appropriate because many patients  
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6 reported that they were able to complete the procedure themselves after receiving the individualized  
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9 intervention. Patient navigation has been gaining interest as an approach to reducing disparities in  
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12 cancer screening and diagnosis.[21] This was an essential component of the CM intervention.  
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15 In this study, providers perceived that it was easy to understand the content of and administer  
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17 the intervention. This suggests that it is likely to be “feasible” for implementing in routine clinical  
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19 practice. However, there are also challenges to the implementation of the intervention in a clinical  
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21 setting in terms of resources. In particular, providers considered it would be difficult to deliver the  
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23 intervention to all eligible patients simultaneously. Thus, it may be necessary to adopt strategies  
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25 according to the resources available at each facility, such as providing the intervention initially to  
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27 patients within reach and eventually to all individuals.  
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#### 38 **4.4 Limitations**

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40 First, the intervention was provided in only two hospitals. In addition, only three staff members with  
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42 long clinical experience participated in the interviews to evaluate the intervention. Because this study  
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44 was not conducted across different regions, differently sized psychiatric hospitals, or in staff with  
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46 varied experience, the generalizability of the results may be limited. Second, we only examined the  
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48 opinions of patients who had consented to participation in the RCT for cancer screening  
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50 encouragement. This may lead to an overestimation of acceptability from the patients’ perspective due  
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59 to volunteer bias.[22]  
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## 5. CONCLUSION

The most essential component of the CM intervention according to patients was the in-person counseling with an explanation of colorectal cancer screening by psychiatric care providers. From the psychiatric care providers' perspective, the CM approach to encourage participation in colorectal cancer screening was considered acceptable and appropriate. Although offering the intervention to all patients eligible for cancer screening simultaneously may be difficult, the results indicated that the intervention is easy to understand and administer. Further research is needed to implement this intervention in routine clinical practice.

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### Contributors

YY1, MF1, TS, MK, TM1, YY2, MF2, HT, YU, and MI developed the intervention procedures. YY1, MF1, TS, MK, RS, TM1, YY2, MF2, HT, NN, TM2, SH2, KH, HO, YU, NY, and MI participated in the design of the study. MK, RS, TM1, YY2, and SH1 conducted the investigation. SH2 played a primary role in designing the statistical analysis. YY1, MF1, and TE conducted the qualitative analysis. TM2 played a primary role in designing the data management approach. YY1 and MF1 drafted the manuscript. All authors revised the manuscript and approved the final version.

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### Competing interests

Yuto Yamada reports personal fees from Meiji and Sumitomo Dainippon outside the submitted work.

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Astellas, MSD, Takeda, Fujifilm, Shionogi, and Mochida outside of the submitted work. All other

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6 authors have nothing to disclose.  
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### 10 11 12 **Patient consent for publication** 13

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15 Not required.  
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### 18 19 20 21 **Ethics approval** 22

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24 This study was approved by the institutional ethics committee at the Okayama University Graduate  
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26 School of Medicine, Dentistry, and Pharmaceutical Sciences and Okayama University Hospital on 23  
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28 April 2019 (approval number: RIN1904-003). In addition, this study was approved by the Okayama  
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30 Psychiatric Medical Center (approval number: 1-1) and by the Zikei Hospital (approval number:  
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32 146gou-1-5) as well as by the J-SUPPORT Scientific Advisory Board.  
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### 42 **Data sharing statement** 43

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45 The datasets in this study are not publicly available because of the terms of consent to which the  
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47 participants agreed but may be available from the corresponding author on reasonable request.  
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## 51 52 53 **6. REFERENCES** 54

- 55  
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57 1. Crump C, Winkleby MA, Sundquist K, et al. Comorbidities and mortality in persons with  
58  
59  
60

- 1  
2  
3  
4  
5  
6 schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170(3):324–33.  
7  
8  
9 <https://doi.org/10.1176/appi.ajp.2012.12050599>.  
10  
11  
12 2. Olfson M, Gerhard T, Huang C, et al. Premature mortality among adults with schizophrenia in  
13  
14 the United States. *JAMA Psychiatry* 2015;72(12):1172–81.  
15  
16 <https://doi.org/10.1001/jamapsychiatry.2015.1737>.  
17  
18  
19 3. Pettersson D, Gissler M, Hällgren J, et al. The overall and sex- and age-group specific incidence  
20  
21 rates of cancer in people with schizophrenia: a population-based cohort study. *Epidemiol*  
22  
23 *Psychiatr Sci* 2020;29:e132. <https://doi.org/10.1017/S204579602000044X>.  
24  
25  
26  
27  
28  
29 4. Zhuo C, Tao R, Jiang R, et al. Cancer mortality in patients with schizophrenia: systematic review  
30  
31 and meta-analysis. *Br J Psychiatry* 2017;211(1):7–13.  
32  
33 <https://doi.org/10.1192/bjp.bp.116.195776>.  
34  
35  
36  
37  
38  
39 5. Hwong AR, Mangurian C. Improving breast cancer screening and care for women with severe  
40  
41 mental illness. *J Clin Oncol* 2017;35(36):3996–8. <https://doi.org/10.1200/JCO.2017.76.0462>.  
42  
43  
44  
45 6. Solmi M, Firth J, Miola A, et al. Disparities in cancer screening in people with mental illness  
46  
47 across the world versus the general population: prevalence and comparative meta-analysis  
48  
49 including 4 717 839 people. *Lancet Psychiatry* 2020;7(1):52–63. [https://doi.org/10.1016/S2215-](https://doi.org/10.1016/S2215-0366(19)30414-6)  
50  
51  
52  
53  
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60 0366(19)30414-6.  
7. Fujiwara M, Inagaki M, Nakaya N, et al. Cancer screening participation in schizophrenic



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2  
3  
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7 outpatients and the influence of their functional disability on the screening rate: A cross-sectional  
8  
9 study in Japan. *Psychiatry Clin Neurosci* 2017;71(12):813–25.  
10  
11 <https://doi.org/10.1111/pcn.12554>.  
12  
13  
14  
15 8. Shin DW, Chang D, Jung JH, et al. Disparities in the participation rate of colorectal cancer  
16  
17 screening by fecal occult blood test among people with disabilities: a national database study in  
18  
19 South Korea. *Cancer Res Treat* 2020;52(1):60–73. <https://doi.org/10.4143/crt.2018.660>.  
20  
21  
22  
23  
24 9. Fujiwara M, Higuchi Y, Nakaya N, et al. Trends in cancer screening rates among individuals  
25  
26 with serious psychological distress: an analysis of data from 2007 to 2016 Japanese national  
27  
28 surveys, *J Psychosoc Oncol Res Pract* 2020;2(3):e025.  
29  
30  
31 <https://doi.org/10.1097/OR9.0000000000000025>.  
32  
33  
34  
35  
36 10. Fujiwara M, Inagaki M, Shimazu T, et al. A randomised controlled trial of a case management  
37  
38 approach to encourage participation in colorectal cancer screening for people with schizophrenia  
39  
40 in psychiatric outpatient clinics: study protocol for the J-SUPPORT 1901 (ACCESS) study. *BMJ*  
41  
42 *Open* 2019;9(11):e032955. <https://doi.org/10.1136/bmjopen-2019-032955>.  
43  
44  
45  
46  
47  
48 11. Fujiwara M, Yamada Y, Shimazu T, et al. Encouraging participation in colorectal cancer  
49  
50 screening for people with schizophrenia: a randomized controlled trial. *Acta Psychiatr Scand*  
51  
52 2021;144(4):318–28. <https://doi.org/10.1111/acps.13348>.  
53  
54  
55  
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57 12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual  
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- distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;38(2):65–76. <https://doi.org/10.1007/s10488-010-0319-7>.
13. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Washington, DC: American Psychiatric Association Publishing, 2013.
14. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17(1):88. <https://doi.org/10.1186/s12913-017-2031-8>.
15. Cabinet Office, Government of Japan, Public Opinion Survey on Cancer Control (in Japanese). <https://survey.gov-online.go.jp/h28/h28-gantaisaku/2-2.html> [Accessed 19 Oct 2021].
16. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the health belief model. *Health Education Quarterly* 1988;15(2):175–83. <https://doi.org/10.1177/109019818801500203>
17. Proctor EK, Landsverk J, Aarons G, et al. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Adm Policy Ment Health* 2009;36(1):24–34. <https://doi.org/10.1007/s10488-008-0197-4>.
18. Irwin KE, Henderson DC, Knight HP, et al. Cancer care for individuals with schizophrenia. *Cancer* 2014;120(3):323–34. <https://doi.org/10.1002/cncr.28431>.
19. Weinstein LC, Stefancic A, Cunningham AT, et al. Cancer screening, prevention, and treatment in people with mental illness. *CA Cancer J Clin* 2016;66(2):134–51.

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<https://doi.org/10.3322/caac.21334>.

20. Friedman LC, Puryear LJ, Moore A, et al. Breast and colorectal cancer screening among low-income women with psychiatric disorders. *Psychooncology* 2005;14(9):786–91.

<https://doi.org/10.1002/pon.906>.

21. Wells KJ, Battaglia TA, Dudley DJ, et al. Patient navigation: state of the art or is it science? *Cancer* 2008;113(8):1999–2010. <https://doi.org/10.1002/cncr.23815>.

22. Tarquinio C, Kivits J, Minary L, et al. Evaluating complex interventions: perspectives and issues for health behaviour change interventions. *Psychol Health* 2015;30(1):35–51.

<https://doi.org/10.1080/08870446.2014.953530>.

## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	p.1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	p.4, 5

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	p. 7, 8
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	p. 8

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	p. 9
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	p. 15
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	p. 9-11
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	p. 9, 10
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	p. 9
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	p. 15

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	p.14, 15
6 7 8	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	p. 16, 17
9 10 11 12	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	p. 15
13 14 15 16	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	p. 15
17 18 19 20	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	p. 14, 15

### Results/findings

23 24 25 26	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	p. 16-33
27 28 29	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	p. 19-28

### Discussion

32 33 34 35 36 37	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	p. 29-32
38 39	<b>Limitations</b> - Trustworthiness and limitations of findings	p. 32, 33

### Other

42 43 44	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	p. 35, 36
45 46	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	p. 34, 35

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

For peer review only

# BMJ Open

## Patients' acceptability and implementation outcomes of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia: a qualitative secondary analysis of a mixed-method randomized clinical trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-060621.R1
Article Type:	Original research
Date Submitted by the Author:	12-Apr-2022
Complete List of Authors:	<p>Yamada, Yuto; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Neuropsychiatry; Okayama University Hospital, Department of Neuropsychiatry  Fujiwara, Masaki; Okayama University Hospital, Department of Neuropsychiatry  Shimazu, Taichi; National Cancer Center, Division of Behavioral Sciences, Institute for Cancer Control  Etoh, Tsuyoshi; Shimane University Hospital, Department of Nursing  Kodama, Masafumi; Okayama Psychiatric Medical Center  So, Ryuhei ; Okayama Psychiatric Medical Center  Matsushita, Takanori; Zikei Hospital  Yoshimura, Yusaku; Zikei Hospital  Horii, Shigeo; Zikei Hospital  Fujimori, Maiko; National Cancer Center Institute for Cancer Control, Division of Supportive Care, Survivorship and Translational Research  Takahashi, Hirokazu ; National Cancer Center Institute for Cancer Control, Division of Screening Assessment and Management  Nakaya, Naoki; Tohoku University, Tohoku Medical Megabank Organization  Miyaji, Tempei; The University of Tokyo, Department of Clinical Trial Data Management, Graduate School of Medicine  Hinotsu, Shiro ; Sapporo Medical University, Department of Biostatistics and Data Management  Harada, Keita; Okayama University Hospital, Department of Gastroenterology  Okada, Hiroyuki; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Gastroenterology and Hepatology  Uchitomi , Yosuke; National Cancer Center Institute for Cancer Control, Group for Supportive Care and Survivorship Research  Yamada, Norihito; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Neuropsychiatry  Inagaki, Masatoshi; Shimane University, Department of Psychiatry, Faculty of Medicine</p>
<b>Primary Subject Heading</b>:	Mental health

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Secondary Subject Heading:	Oncology
Keywords:	Schizophrenia & psychotic disorders < PSYCHIATRY, QUALITATIVE RESEARCH, ONCOLOGY







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1 **Title**

2 Patients' acceptability and implementation outcomes of a case management approach to encourage  
3 participation in colorectal cancer screening for people with schizophrenia: a qualitative secondary  
4 analysis of a mixed-method randomized clinical trial

6 **Authors**

7 Yuto Yamada, MD<sup>1, 2</sup>, Masaki Fujiwara MD, PhD<sup>2\*</sup>, Taichi Shimazu, MD, PhD<sup>3</sup>, Tsuyoshi Etoh,  
8 MS<sup>4</sup>, Masafumi Kodama, MD, PhD<sup>5</sup>, Ryuhei So, MD, MPH<sup>5</sup>, Takanori Matsushita, MD<sup>6</sup>, Yusaku  
9 Yoshimura, MD, PhD<sup>6</sup>, Shigeo Horii, MD, PhD<sup>6</sup>, Maiko Fujimori, PhD<sup>7</sup>, Hirokazu Takahashi, MD,  
10 PhD<sup>8</sup>, Naoki Nakaya, PhD<sup>9</sup>, Tempei Miyaji, MSc<sup>10, 11</sup>, Shiro Hinotsu, MD, PhD<sup>12</sup>, Keita Harada, MD,  
11 PhD<sup>13</sup>, Hiroyuki Okada, MD, PhD<sup>14</sup>, Yosuke Uchitomi, MD, PhD<sup>15</sup>, Norihito Yamada, MD, PhD<sup>1</sup>,  
12 Masatoshi Inagaki, MD, PhD<sup>16\*</sup>

14 **Affiliations**

15 <sup>1</sup>Department of Neuropsychiatry, Okayama University Graduate School of Medicine, Dentistry, and  
16 Pharmaceutical Sciences, Okayama, Japan

17 <sup>2</sup>Department of Neuropsychiatry, Okayama University Hospital, Okayama, Japan

18 <sup>3</sup>Division of Behavioral Sciences, Institute for Cancer Control, National Cancer Center, Tokyo, Japan

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4  
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6  
7 19 <sup>4</sup>Department of Nursing, Shimane University Hospital, Izumo, Japan  
8  
9  
10 20 <sup>5</sup>Okayama Psychiatric Medical Center, Okayama, Japan  
11  
12  
13 21 <sup>6</sup>Zikei Hospital, Okayama, Japan  
14  
15  
16 22 <sup>7</sup>Division of Supportive Care, Survivorship and Translational Research, National Cancer Center  
17  
18 23 Institute for Cancer Control, Tokyo, Japan  
19  
20  
21 24 <sup>8</sup>Division of Screening Assessment and Management, National Cancer Center Institute for Cancer  
22  
23  
24 25 Control, Tokyo, Japan  
25  
26  
27 26 <sup>9</sup>Tohoku Medical Megabank Organization, Tohoku University, Sendai, Japan  
28  
29  
30 27 <sup>10</sup>Department of Clinical Trial Data Management, Graduate School of Medicine, The University of  
31  
32  
33 28 Tokyo, Tokyo, Japan  
34  
35  
36 29 <sup>11</sup>Behavioral Sciences and Survivorship Research Group, Center for Public Health Sciences, National  
37  
38  
39 30 Cancer Center, Tokyo, Japan  
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41  
42 31 <sup>12</sup>Department of Biostatistics and Data Management, Sapporo Medical University, Sapporo, Japan  
43  
44  
45 32 <sup>13</sup>Department of Gastroenterology, Okayama University Hospital, Okayama, Japan  
46  
47  
48 33 <sup>14</sup>Department of Gastroenterology and Hepatology, Okayama University Graduate School of  
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50  
51 34 Medicine, Dentistry and Pharmaceutical Sciences, Okayama, Japan  
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54 35 <sup>15</sup>National Cancer Center Institute for Cancer Control, Group for Supportive Care and Survivorship  
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57 36 Research, Tokyo, Japan  
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6 37 <sup>16</sup>Department of Psychiatry, Faculty of Medicine, Shimane University, Izumo, Japan  
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8

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11  
12 39 **\*Correspondence**  
13

14  
15 40 Masaki Fujiwara, M.D., Ph.D.  
16

17  
18 41 Department of Neuropsychiatry, Okayama University Hospital  
19

20  
21 42 2-5-1 Shikata-cho, Kita-ku, Okayama, Japan  
22

23  
24 43 Tel: +81-86-235-7242  
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26  
27 44 E-mail: [mfujiwara@okayama-u.ac.jp](mailto:mfujiwara@okayama-u.ac.jp)  
28  
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31

32  
33 46 Masatoshi Inagaki, M.D., Ph.D.  
34

35  
36 47 Department of Psychiatry, Faculty of Medicine, Shimane University  
37

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39 48 89-1 Enya-cho, Izumo, Shimane 693-8501, Japan  
40

41  
42 49 Tel: +81-853-20-2262  
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45 50 E-mail: [minagaki@med.shimane-u.ac.jp](mailto:minagaki@med.shimane-u.ac.jp)  
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6 53 **ABSTRACT (300 words)**  
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9 54 **Objectives**  
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12 55 We examined the efficacy of case management (CM) interventions to encourage participation in  
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15 56 colorectal cancer screening for schizophrenia patients. This study aimed to clarify patients'  
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21 58 aimed to determine the acceptability, appropriateness, and feasibility of the intervention from the  
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30 61 **Study design and setting**  
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33 62 This study was a secondary qualitative analysis of a mixed-method randomized controlled trial that  
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36 63 evaluated the efficacy of the CM approach to encourage participation in cancer screening for people  
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39 64 with schizophrenia. The intervention comprised education and patient navigation for colorectal cancer  
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42 65 screening. Interviews were conducted with patients who received the intervention and staff from two  
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45 66 psychiatric hospitals in Japan who delivered the intervention.  
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51 68 **Participants**  
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54 69 Of the 172 patients with schizophrenia who participated in the trial, 153 were included. In addition,  
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57 70 three out of six providers were included.  
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10 72 **Data collection and analysis**

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12 73 Using a structured interview, the case manager asked participants about patient acceptability and  
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15 74 helpful components of the intervention. Content analysis was conducted for the responses obtained,  
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18 75 and the number of responses was tabulated by two researchers. For the interviews with the providers,  
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21 76 opinions obtained from verbatim transcripts were extracted and summarized.  
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27 78 **Results**

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30 79 Forty-three of the 56 patients perceived that the intervention was acceptable. For the intervention  
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33 80 component, in-person counseling with an explanation of the screening process by psychiatric care  
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36 81 providers was most frequently reported as helpful by patients (48 of the 68 respondents). Psychiatric  
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39 82 care providers evaluated the intervention as acceptable, appropriate, and easy to understand and  
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42 83 administer. However, providing the intervention to all patients simultaneously was considered difficult  
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45 84 with the current human resources.  
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51 86 **Conclusions**

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54 87 This study showed that the CM intervention was perceived as acceptable by patients and acceptable  
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57 88 and appropriate by psychiatric care providers.  
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10 **90 Keywords**

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12 91 Cancer screening, schizophrenia, case management, patient navigation, mixed-method randomized  
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15 92 controlled trial  
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21 **94 Trial registration**

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24 95 UMIN000036017  
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31 **97 Strengths and limitations of the study**

- 32 98 • This study was designed to incorporate a pre-planned qualitative study into a randomized  
33 99 controlled trial.  
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36 100 • Information related to the implementation of the intervention, as assessed by patients and  
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39 101 psychiatric care providers, was organized according to theoretical frameworks.  
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42 102 • Acceptability from the patients' perspective may be overestimated because we only examined  
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45 103 the opinions of patients who consented to the randomized controlled trial for cancer screening  
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48 104 encouragement.  
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51 105 • We did not investigate psychiatric hospitals of all sizes/regions, which limits the generalizability  
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54 106 of the present results.  
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6 108 **1. BACKGROUND**  
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9 109 Cancer is a leading cause of death among people with schizophrenia, and cancer mortality in those  
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12 110 with schizophrenia is greater than that in the general population.[1, 2] Delayed cancer detection is one  
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15 111 factor that contributes to the high cancer mortality rates in this population.[3,4] Therefore, there is a  
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18 112 crucial need to encourage guideline-recommended screening in patients with schizophrenia.[5]  
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21 113 A previous study showed disparities in cancer screening among people with  
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24 114 schizophrenia.[6, 7] Moreover, such disparities in cancer screening among people with a mental  
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27 115 illness have persisted or become even wider.[8, 9] Therefore, we developed a case management  
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30 116 (CM) approach to encourage participation in cancer screening, with a particular focus on colorectal  
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33 117 cancer screening using a fecal occult blood test (FOBT), for patients with schizophrenia in  
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36 118 psychiatric outpatient clinics.[10] In psychiatric medical settings, CM, which includes the planning  
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39 119 and coordinating of necessary services for community life, is commonly implemented. CM may also  
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42 120 include advice on maintaining physical health and referral to appropriate specialists. The present  
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45 121 intervention provided education and navigation regarding cancer screening as a part of CM in daily  
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48 122 clinical practice.  
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51 123 The efficacy of this intervention has been confirmed by a randomized controlled trial  
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54 124 (RCT).[11] For the next step, it is necessary to confirm the effectiveness of this intervention in  
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57 125 routine clinical settings. However, to implement a new intervention in routine clinical practice, it is  
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6 126 valuable to determine patients' acceptability of the intervention and identify components of the  
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9 127 intervention that patients perceive as helpful. This is because the intervention is complex and  
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12 128 includes personal education and navigation for cancer screening. Furthermore, it is necessary to  
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15 129 examine implementation outcomes, such as acceptability, appropriateness, and feasibility,[12] as  
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18 130 perceived by psychiatric care providers.  
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21 131 During this trial, we conducted a pre-planned qualitative study to determine the information  
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24 132 needed to carry out future implementation research. In this qualitative study, we first aimed to evaluate  
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27 133 patients' acceptability of the intervention, identify helpful components of the intervention, and explore  
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29  
30 134 the reasons for participation or non-participation in cancer screening. Second, we examined the  
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33 135 acceptability, appropriateness, and feasibility of the intervention as assessed by psychiatric care  
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36 136 providers.  
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## 40 41 138 **2. METHODS**

### 42 43 44 139 **2.1 Study design and participants**

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47 140 This study was a secondary analysis of a mixed-method RCT that evaluated the efficacy of the CM  
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50 141 approach to encourage participation in cancer screening for people with schizophrenia. In this RCT,  
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53 142 we interviewed study participants and psychiatric care providers who administered the intervention.  
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56 143 All participants provided written informed consent prior to enrollment. This study is registered in the  
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59 144 UMIN Clinical Trials Registry (UMIN000036017). The protocol of the trial, details of the intervention,  
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6 145 and main trial findings were reported elsewhere.[10, 11] Therefore, the method of the trial is described  
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9 146 briefly.

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12 147 We recruited patients from two psychiatric outpatient clinics in Okayama City in Japan: the  
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15 148 Okayama Psychiatric Medical Center (252 beds and approximately 250 outpatient visits per day) and  
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18 149 Zikei Hospital (570 beds and approximately 160 outpatient visits per day). Eligible participants were  
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21 150 aged  $\geq 40$  years in the 2019 fiscal year; had visited the recruitment sites as their primary psychiatric  
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23  
24 151 outpatient service; and were outpatients diagnosed by their current primary psychiatrist with  
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27 152 schizophrenia or schizoaffective disorder, according to the Diagnostic and Statistical Manual of  
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29  
30 153 Mental Disorders, Fifth Edition.[13] Key exclusion criteria were patients with a history of colorectal  
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33 154 cancer; those living in an institution where residents were supported in receiving cancer screening;  
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35  
36 155 and patients judged to be at risk of symptom worsening by participating in the study.

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39 156 Patients were randomly assigned to receive usual intervention, which included municipal  
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42 157 public education (treatment as usual: TAU group), or an intervention to encourage participation in  
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45 158 cancer screening using CM plus TAU (CM plus TAU group).

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## 50 51 160 **2.2 Cancer screening program provided by the municipality**

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54 161 In Japan, the Ministry of Health, Labour and Welfare (MHLW) recommends population-based cancer  
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57 162 screening for colorectal, gastric, lung, breast, and cervical cancer. These screenings are provided by  
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6 163 local governments with a low co-payment. In this study, we recommended colorectal cancer screening  
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9 164 using the FOBT for individuals aged 40 years and older. The cancer screening program of Okayama  
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12 165 City does not mail the FOBT kit in advance. Instead, individuals select a clinic offering cancer  
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15 166 screening and make an appointment to visit the clinic to receive the kit. Although individuals with a  
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18 167 low household income can receive free screening, eligible individuals must apply for a coupon in  
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21 168 advance at the municipal office.  
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23  
24 169 The Okayama municipal government distributes a leaflet and detailed brochure encouraging  
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26  
27 170 participation in the above cancer screening program to all households in the city once a year.  
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### 32 33 172 **2.3 Case management intervention to encourage participation in cancer screening**

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36 173 A case manager (nurse or psychiatric social worker) provided three counseling sessions to the study  
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39 174 participants allocated to the CM plus TAU group. The CM intervention aimed to educate and navigate  
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42 175 patients around colorectal cancer screening.  
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45 176 The first session, which was conducted in person, comprised the following components: a)  
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48 177 education on the importance and content of colorectal cancer screening, using a pamphlet, b)  
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51 178 assistance in making decisions and an appointment for colorectal cancer screening, and c) assistance  
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54 179 in obtaining a coupon for free screening, if necessary. Other cancer screening was also briefly  
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57 180 mentioned using the pamphlet. Education on cancer screening using the pamphlet did not take the  
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6 181 approach whereby the seriousness or severity of cancer was emphasized.  
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9 182 After the first in-person session, a case manager provided at least two follow-up in-person  
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12 183 or telephone counseling sessions to remind or support the patient's participation in cancer screening.  
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15 184 The follow-up session could be skipped if the subject was judged to be able to receive cancer screening  
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18 185 without the follow-up sessions. This judgment was made by case managers according to their clinical  
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21 186 assessment of the patient's functioning.  
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24 187 This intervention was standardized in the form of a manual. Psychiatric nurses or social  
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27 188 workers who had already worked at the study sites administered the intervention as case managers,  
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29  
30 189 according to the procedures described in the manual. The intervention was administered during  
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33 190 patients' outpatient visits. In Japan, the MHLW requires that primary care physicians encourage their  
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36 191 patients to undergo cancer screening. The present intervention is consistent with the national policy  
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39 192 for cancer screening.  
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#### 43 44 45 194 **2.4 Follow-up interview conducted after the end of the intervention period** 46

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48 195 After the end of the municipal cancer screening period, qualitative follow-up interviews were  
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51 196 conducted with both case managers and study participants between January 2020 and March 2020.  
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#### 55 56 57 198 **2.4.1 Interviews with patients** 58 59 60

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6 199 In a structured interview, the case manager asked the CM plus TAU group participants about “patients’  
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9 200 acceptability of the intervention,” “helpful components of the intervention,” and “reasons for  
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12 201 participation or non-participation in cancer screening.”

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15 202 *For patients’ acceptability of the intervention*, patients were asked about “affective attitude,”  
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17  
18 203 which is one of the components of the theoretical framework of acceptability.[14] This theoretical  
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21 204 framework was developed according to the overview of systematic reviews focusing on patients’  
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23  
24 205 acceptability of healthcare interventions.[14] We selected the affective attitude that was considered  
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26  
27 206 most helpful in disseminating the intervention. Patients were asked, “how do you feel about this  
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30 207 recommendation for cancer screening?”

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33 208 *For helpful components of the intervention*, patients were asked to describe the components  
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36 209 of the intervention that they perceived as helpful. The interviewer categorized patients’ open-ended  
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39 210 responses into the following components of the intervention: assignment of a case manager;  
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42 211 explanation of colorectal cancer screening; explanation of the coupon for free screening; planning a  
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45 212 schedule for the cancer screening; and follow-up contact at a later date. Patients were asked, “what  
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48 213 was helpful in this intervention?”

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51 214 *For reasons for participation or non-participation in cancer screening*, patients were asked  
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54 215 to describe their reasons for participation or non-participation with an open-ended question. The  
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57 216 interviewers categorized patients’ responses into predetermined options, which were based on a  
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6 217 Japanese public opinion survey on cancer control,[15] and were classified into the following categories  
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9 218 based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits;  
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12 219 perceived barriers; cue to action; and self-efficacy.[16] Patients were asked, “what were your reasons  
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14  
15 220 for participating or not participating in colorectal cancer screening?”  
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18 221 The interviewer summarized the content immediately after the responses were obtained, and  
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21 222 the interviews with patients were not recorded.  
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#### 27 224 **2.4.2 Interviews with providers**

29  
30 225 A group interview was conducted with providers to assess the implementation outcomes of the  
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33 226 intervention. Proctor et al. proposed the Implementation Outcomes Framework,[17] which  
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36 227 conceptualizes the variables of interest in implementation evaluation. Among the implementation  
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39 228 outcomes included in this framework, we investigated “acceptability,” “appropriateness,” and  
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42 229 “feasibility,” which were all measurable factors in this study.  
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45 230 *Acceptability* is defined as the perception among providers that an intervention is agreeable,  
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48 231 palatable, or satisfactory.[12] For “acceptability,” providers were asked, “what do you think about this  
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51 232 intervention in terms of whether it is an agreeable, palatable, or satisfactory intervention?”  
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54 233 *Appropriateness* is defined as the perceived fit, relevance, or compatibility of the  
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57 234 intervention for providers.[12] In this study, providers were asked, “did this intervention meet the  
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6 235 objective of improving cancer screening uptake among people with schizophrenia?” and “were the

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9 236 components of the intervention fit for purpose to make the intervention effective?”

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12 237 *Feasibility* is defined as the extent to which an intervention can be successfully used or

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15 238 carried out within a given setting.[12] In this study, providers were asked, “would this intervention be

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18 239 feasible to implement in a routine psychiatric outpatient setting?”

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21 240 Two case managers who administered the intervention and a psychiatrist who was involved

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24 241 in the recruitment of the subjects participated in this study. One researcher (M.F1., a psychiatrist with

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27 242 14 years of clinical experience) acted as the interviewer and facilitated discussions on the

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30 243 “acceptability,” “appropriateness,” and “feasibility” of the intervention.[11] The interview was

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33 244 recorded, and a verbatim transcript was produced.

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38 246 **2.5 Data analysis**

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41 247 For the analysis of patient responses, those whose self-reports of receiving colorectal cancer screening

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44 248 did not match the municipal records of the screening were excluded from the analysis to improve the

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47 249 validity of the results. For “patients’ acceptability of the intervention,” content analysis was performed

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50 250 on the patients’ responses described by interviewers. The open-ended responses were coded following

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53 251 a discussion between two researchers (YY, a psychiatrist with 6 years of clinical experience, and TE,

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56 252 a nurse with more than 10 years of clinical experience), and the number of responses was tabulated

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59 253 according to the codes created. For “helpful components of the intervention,” “reasons for

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6 254 participation in cancer screening,” and “reasons for non-participation in cancer screening,” the open-  
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9 255 ended responses obtained from the interviews were categorized into predetermined options by the  
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12 256 interviewers. Answers that did not fit into the predetermined options were coded by the same  
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15 257 researchers, and the number of responses was tabulated according to the codes created. Responses to  
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18 258 “patients’ acceptability of the intervention” and “helpful components of the intervention” were  
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20  
21 259 stratified according to whether patients had received cancer screening.  
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24 260 For the data obtained from the interviews with providers, the researcher extracted and  
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27 261 summarized the opinions obtained from the verbatim transcripts and asked the interviewees to revise  
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30 262 and confirm the summarized descriptions.  
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## 36 264 **2.6 Patient and public involvement statement**

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39 265 Patients were not directly involved in the development of the research questions and interventions or  
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42 266 in the design of the planned study. We obtained patients’ feedback regarding the intervention in this  
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45 267 study. The results of the study will be published on our facilities’ and funder’s website.  
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## 51 269 **3. RESULTS**

### 54 270 **3.1 Patient enrollment and baseline characteristics**

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57 271 Between June 3, 2019, and September 9, 2019, 172 eligible participants were randomly assigned to  
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6 272 either the CM plus TAU group (n = 86) or the TAU group (n = 86). Eighty participants in the CM plus  
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9 273 TAU group (94.1%) and 83 participants in the TAU group (97.6%) took part in the follow-up  
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11  
12 274 interview. Of these, self-reports on whether they had received colorectal cancer screening were  
13  
14  
15 275 consistent with the results of the inquiry by Okayama City in 78 participants in the CM plus TAU  
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18 276 group and 75 participants in the TAU group. There were inconsistencies between the self-reported  
19  
20  
21 277 results and the city's records for two participants in the CM plus TAU group and eight participants in  
22  
23  
24 278 the TAU group. The background information of the included 153 participants is shown in Table 1.  
25  
26  
27 279 Thirty-nine participants (50.0%) in the CM plus TAU group and one participant (10.0%) in the TAU  
28  
29  
30 280 group received cancer screening. Of these, seven participants in the CM plus TAU group and one in  
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33 281 the TAU group required detailed examinations, such as colonoscopy, and all of these participants  
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36 282 reported that they had undergone the prescribed detailed examination.  
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285 **Table 1. Patient characteristics**

	Case management intervention plus treatment as usual (N = 78)	Treatment as usual (N = 75)	Total (N = 153)
<b>Age, years</b>			
Median (range)	52 (39, 74)	54 (39, 80)	53 (39, 80)
<b>Sex</b>			
Women	37 (47.4%)	35 (46.7%)	72 (47.1%)
<b>Educational level*</b>			
≤ Junior high school	18 (23.1%)	15 (20.0%)	31 (20.3%)
> Junior high school but ≤ high school	36 (46.2%)	38 (50.7%)	74 (48.4%)
> High school but ≤ junior/vocational college	8 (10.3%)	9 (12.0%)	17 (11.1%)
≥ University or college	16 (20.5%)	13 (17.3%)	29 (19.0%)
<b>Marital status*</b>			
Married	9 (11.5%)	8 (10.7%)	17 (11.1%)
<b>Living alone*</b>			
Yes	39 (50.0%)	36 (48.0%)	75 (49.0%)
<b>Current outpatient for physical illness*</b>			
Yes	38 (48.7%)	35 (46.7%)	73 (47.7%)
<b>History of receiving colorectal cancer screening*</b>			
Yes	35 (44.9%)	30 (40.0%)	65 (42.5%)
No	43 (55.1%)	44 (58.7%)	87 (56.9%)
Unknown	0 (0%)	1 (1.3%)	1 (0.7%)
<b>mGAF score</b>			
Mean (SD)	49.6 (15.7)	50.9 (14.8)	50.2 (15.2)
Range	15, 85	25, 85	15, 85
<b>Participation in colorectal cancer screening</b>			
Received colorectal cancer screening	39 (50.0%)	10 (13.3%)	49 (32.0)
Needed a detailed examination*	7 (17.9%)	1 (10.0%)	8 (16.3%)
Received a detailed examination*	7 (100%)	1 (100%)	8 (100%)
<b>Results of detailed examination*</b>			
A polyp was detected and resected	3 (42.9%)	0 (0%)	3 (37.5%)
Hemorrhoid	1 (14.3%)	0 (0%)	1 (12.5%)
Enteritis	1 (14.3%)	0 (0%)	1 (12.5%)
No abnormal findings	2 (28.6%)	1 (0%)	3 (37.5%)

286 \*Self-reported.

287 Abbreviations: mGAF, modified global assessment of functioning; SD, standard deviation.

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289 **3.2 Patients' acceptability and helpful components of the intervention**

290 Table 2 shows the responses obtained from patients regarding their impressions of the intervention.

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6 291 Of the 78 patients in the CM plus TAU group, 56 responded, of whom 30 received colorectal cancer  
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9 292 screening and 26 did not.  
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For peer review only

295 **Table 2. Patients' acceptability of the intervention\***

	<b>Patients of CM plus TAU group who responded</b>	
	<b>Uptake of colorectal cancer screening</b>	
	<b>Yes (N = 30)</b>	<b>No (N = 26)</b>
I was satisfied with the encouragement.	29	14
It was very good.	14	4
It was a good opportunity to receive cancer screening.	9	0
The explanations of cancer screening and the screening procedure were helpful.	3	4
I am glad that the polyp was treated quickly.	2	0
I would like this recommendation to be continued.	1	0
I felt it was important to have cancer screening.	1	6
It was not uncomfortable to be encouraged.	-†	1
I felt I did not need to undergo the screening right now.	-†	9
I felt it was bothersome.	1	1
I felt suspicious when they said "research."	-†	1

296 \*Multiple answers allowed. Patients were asked to provide open-ended responses. Content analysis  
 297 was performed by the researchers, and the number of responses was tabulated according to the codes  
 298 created.

299 †No responses on this content were obtained. Patients were not asked their opinion on this content in  
 300 a close-ended question.

301 Abbreviations: CM, case management; TAU, treatment as usual.

302 Of the 39 patients in the CM plus TAU group who received colorectal cancer screening, 30 (76.9%)  
 303 responded. Of the 39 patients in CM plus TAU group who did not receive screening, 26 (66.7%)  
 304 responded.

305 One patient provided multiple responses, stating that "the explanation of cancer screening and the  
 306 screening procedure were helpful" and "I would like this recommendation to be continued."

307

308 Of the 30 patients who underwent colorectal cancer screening, 29 reported that they were  
 309 satisfied with the encouragement. Specifically, the following comments were made by participants:

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6 310 *“It was very good, please continue next year.” ID 111*

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9 311 *“I am glad that a polyp was found and treated quickly.” ID 136*

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12 312 Of the 26 patients who did not undergo cancer screening, 14 said they were satisfied with  
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15 313 the encouragement. In addition, one patient voluntarily stated that they did not consider it  
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18 314 uncomfortable to be encouraged. However, of the patients who did not undergo cancer screening, nine  
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21 315 responded that they felt they did not need to undergo screening at the time. Specifically, the following  
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24 316 comments were obtained:

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27 317 *“It’s not necessary for me, so it doesn’t matter if you explain it to me.” ID 55*

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30 318 Table 3 shows the responses from patients regarding the components of the intervention  
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33 319 which were considered helpful. Among the patients in the CM plus TAU group who underwent cancer  
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36 320 screening, the most common response was “explanation of colorectal cancer screening,” which was  
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39 321 deemed helpful by 31 (81.6%) patients. This was followed by “assignment of a case manager” and  
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42 322 “explanation of the coupon for free screening,” which were considered helpful by 19 (50.0%) and 17  
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44  
45 323 (47.4%) patients, respectively.

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326 **Table 3. Helpful components of the intervention\***

	Patients of the CM plus TAU group who responded (N = 68)			
	Uptake of colorectal cancer screening			
	Yes (N = 38)		No (N = 30)	
	N	%	N	%
Assignment of a case manager	19	50.0	8	26.7
Explanation of colorectal cancer screening	31	81.6	17	56.7
Explanation of the coupon for free screening	17	47.4	10	33.3
Planning a schedule for the cancer screening	4	13.2	2	6.7
Follow-up contact at a later date	15	39.5	5	16.7
No helpful points	5	10.5	8	23.3

327 \*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into  
 328 predetermined options by the interviewers, and the number of responses was tabulated.

329 Abbreviations: CM, case management; TAU, treatment as usual.

330 Of the 39 patients who received colorectal cancer screening in the CM plus TAU group, 38 (97.4%)  
 331 responded. Of the 39 patients who did not receive colorectal cancer screening in the CM plus TAU  
 332 group, 30 (76.9%) responded.

333

### 334 3.3 Reasons for participation or non-participation in cancer screening

335 Table 4 shows the responses obtained from patients regarding their reasons for undergoing colorectal  
 336 cancer screening. The most common response was “because it was encouraged in this study,” which  
 337 was the response of 22 (56.4%) patients. The second most common reason was “because I want to  
 338 prevent cancer/detect cancer early,” which was the response of 16 patients (41.0%). Seven patients  
 339 (17.9%) answered “because I am afraid of cancer.”

340 **Table 4. Reasons for participation in cancer screening\***

Categories	Patients' responses	Patients in CM plus TAU group who received cancer screening (N = 39)	
		N	%
Cue to action	Because it was encouraged in this study.	22	56.4
	Because it was encouraged by the primary psychiatrist.	7	17.9
	Because it was encouraged by my family physician.	1	2.6
	Because it was encouraged by my family.	0	0
	Because I received an invitation from the municipality.	1	2.6
	Because I had an upset stomach.	3	7.7
Perceived susceptibility	Because I was afraid of cancer.	7	17.9
	Because I had a family member with cancer.	4	10.3
	Because I had a friend with cancer.	1	2.6
Perceived benefit	Because I had other physical illnesses.	3	7.7
	Because I want to prevent cancer/detect cancer early.	16	41.0
Self-efficacy	Because I thought I could receive it.	5	12.8
Perceived barriers	Because it was not expensive.	15	38.5
	Because I found a clinic that was easy to visit.	6	15.4
Other	Because I receive cancer screening every year or sometimes.	14	35.9

341 \*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into  
342 predetermined options by the interviewers, and the number of responses was tabulated.

343 Reasons for participation in cancer screening were classified by researchers into the following  
344 categories based on the Health Belief Model: perceived susceptibility; perceived severity; perceived  
345 benefits; perceived barriers; cue to action; and self-efficacy.

346 Reasons for participation in cancer screening among the TAU group participants are shown in  
347 Supplementary Table 1.

348 Abbreviations: CM, case management; TAU, treatment as usual.

349

350 Table 5 shows the responses of patients regarding the reasons for not receiving cancer  
351 screening. The most common reason for not receiving cancer screening was "because it was  
352 bothersome," given by 13 (33.3%) patients. Other common reasons were "I will visit a hospital when

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6 353 necessary” and “lack of knowledge about screening,” which were given by seven (17.9%) and five  
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9 354 (12.8%) patients, respectively. For “lack of knowledge about cancer screening,” patients made the  
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12 355 following comments:

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15 356 *“I didn’t receive it because I have good bowel movements.” ID 67*

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18 357 *“I didn’t receive it because I had already had the screening before, and I thought I didn’t*  
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21 358 *need to take it again.” ID 160*

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24 359 Four patients (10.3%) provided the reason, “failure to receive cancer screening” and made the  
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27 360 following comments:

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30 361 *“I misunderstood the period during which the screening was conducted.” ID 75*

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33 362 *“I was going to see the doctor, but I forgot my coupon for free screening.” ID 4*

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365 **Table 5. Reasons for non-participation in cancer screening\***

Categories	Patients' responses	Patients in the CM plus TAU group who did not receive cancer screening (N = 39)	
		N	%
Perceived barriers	Because it was bothersome.	13	33.3
	Because I did not feel the necessity to receive it every year.	5	12.8
	Because there was no time.	1	2.6
	Because it was a financial burden.	1	2.6
	Because I had anxiety about having tests and being diagnosed with cancer.	1	2.6
	Because of obstacles to transport.	0	0
Perceived severity	Because I will visit a hospital when necessary.	7	17.9
Perceived susceptibility	Because I still have a long way to go before I get cancer.	1	2.6
Lack of knowledge	Because of the lack of knowledge about cancer screening.	2	5.1
Self-efficacy	Because I didn't feel like I could receive it.	0	0
Other	No particular reason.	1	2.6
<b>Content of free description**</b>			
Perceived barriers	Because of failure to receive cancer screening.	4	10.3
	Because of psychiatric symptoms.	4	10.3
Perceived severity	Because of the belief that cancer does not need to be detected/treated early.	1	2.6
Other	Because I recently had a colonoscopy.	2	5.1
	Because I was suspicious of this research.	1	2.6

366 \*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into  
 367 predetermined options by the interviewers, and the number of responses was tabulated.

368 \*\*For responses that did not fit the predetermined options, researchers coded the content as free  
 369 description and tabulated the number of responses.

370 Reasons for non-participation in cancer screening were classified by researchers into the following  
 371 categories based on the Health Belief Model: perceived susceptibility; perceived severity; perceived  
 372 benefits; perceived barriers; cue to action; and self-efficacy.

373 Reasons for non-participation in cancer screening among the TAU group participants are shown in  
 374 Supplementary Table 2.

375 Abbreviations: CM, case management; TAU, treatment as usual.

376

377 **3.4 Acceptability, appropriateness, and feasibility of the intervention from the providers'**378 **perspective**

379 The group interviews were conducted with three of the six providers who were involved in the  
 380 intervention. The providers' backgrounds were a nurse with 20 years of clinical experience, a  
 381 psychiatric social worker with 25 years of clinical experience and a psychiatrist with 11 years of  
 382 clinical experience. The implementation outcomes of "acceptability," "appropriateness," and  
 383 "feasibility" as assessed by the providers are summarized in Table 6.

384

385 **Table 6. Acceptability, appropriateness, and feasibility of the intervention from the providers'**  
 386 **perspective**

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 Acceptability
 

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- It is an acceptable intervention for psychiatric clinics to provide encouragement.

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 Appropriateness
 

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- Maintaining patients' physical health is one of the roles of psychiatric clinics.
- This intervention, which provides explanations and support tailored to each patient, is suited to the aim of enabling people with severe mental illness to have access to cancer screening.
- It is worthwhile to encourage and explain cancer screening in person, rather than only providing materials to encourage screening.
- It is important to explain to patients about the coupon for free screening. Some patients decided to receive screening after discovering it was available for free or at a low cost.
- Most patients were able to make an appointment with the hospital to receive cancer screening by themselves; thus, this intervention was appropriate.
- It is essential that the case manager and the patient choose which hospital to receive cancer screening together.
- Few patients changed their intentions of receiving/not receiving cancer screening during the follow-up session. Therefore, follow-up sessions may not be necessary for all patients.

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 Feasibility
 

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- The intervention does not require time-consuming training sessions. Once explained, it is possible to administer the intervention in accordance with the procedures.
  - The intervention procedure could be conducted in routine clinical practice.
  - The intervention could be administered quickly for patients who have a family physician or a history of receiving cancer screening. As the number of those who have undergone cancer screening increases, the burden on case managers will reduce.
  - It is difficult to encourage all patients eligible for colorectal cancer screening simultaneously because of limited resources. The impact of the COVID-19 epidemic introduced further difficulties.
  - It is difficult to conduct follow-up sessions with the same staff member.
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Regarding “acceptability,” the following comments were made:

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*“There are many patients who think they should receive cancer screening but do not*

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*because they did not know much about cancer screening. It is an acceptable*

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*intervention for psychiatric clinics to provide encouragement that is tailored to the*

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*patient’s functional capabilities.” Psychiatric social worker, 25 years of clinical*

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*experience*

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Regarding “appropriateness,” the following comments were made:

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*“Maintaining patients’ physical health is one of the roles of psychiatric clinics.”*

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*Psychiatrist, 11 years of clinical experience*

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*“It is worthwhile to encourage and explain screening in person. Many patients may not*

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*receive screening if they are only given materials to encourage screening.” Nurse, 20*

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*years of clinical experience*

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*“It is important to explain about the coupon for free screening. Some patients decided*

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6 401 *to receive screening after realizing that it was available for free or at a low cost.”*

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9 402 *Nurse, 20 years of clinical experience*

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12 403 *“Many patients were able to go through the process on their own after receiving the*

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15 404 *explanation. It is an appropriate intervention.” Psychiatric social worker, 25 years of*

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18 405 *clinical experience*

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21 406 *“During the follow-up sessions, few patients changed their intentions of receiving/not*

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24 407 *receiving cancer screening or required additional support. Follow-up sessions may not*

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27 408 *be necessary for all patients.” Psychiatric social worker, 25 years of clinical*

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30 409 *experience*

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33 410 In terms of “feasibility,” the following comments were made:

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36 411 *“This intervention will take some getting used to but will not require time-consuming*

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39 412 *training sessions. Once explained, it is possible to carry out the intervention in*

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42 413 *accordance with the procedures.” Psychiatric social worker, 25 years of clinical*

43  
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45 414 *experience*

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48 415 *“This intervention could be administered quickly for patients who have a history of*

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51 416 *undergoing cancer screening. As the number of those who have undergone cancer*

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54 417 *screening increases, the burden on case managers will be reduced.” Psychiatric social*

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57 418 *worker, 25 years of clinical experience*

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6 419 *“It is difficult to encourage all eligible patients for colorectal cancer screening at once*  
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9 420 *in terms of human resources. The impact of the COVID-19 epidemic made it even more*  
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12 421 *difficult.” Nurse, 20 years of clinical experience*  
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#### 18 424 **4. DISCUSSION**

21 425 In this study, the CM intervention was evaluated as acceptable by patients. In-person counseling with  
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24 426 an explanation of cancer screening by psychiatric care providers was the most common reason for  
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27 427 receiving cancer screening. From the providers’ perspective, the intervention delivered in a psychiatric  
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30 428 outpatient setting was perceived as “acceptable” and “appropriate.” As was intended when the  
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33 429 intervention was developed, the intervention was simple for providers to understand and administer.  
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36 430 However, it was difficult to provide the intervention to all patients simultaneously, which presents a  
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39 431 challenge for its implementation in routine clinical practice. The results of this study may help  
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42 432 implement the CM intervention to encourage participation in colorectal cancer screening in clinical  
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45 433 practice.  
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##### 51 435 **4.1 Patients’ acceptability and helpful components of the intervention**

54 436 From the patients’ perspective, evaluations of the intervention were mostly positive, which suggested  
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57 437 that there is patient demand for this intervention. In addition, few patients, including those who did  
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6 438 not receive colorectal cancer screening, reported any discomfort or anxiety about receiving the  
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9 439 intervention. This suggests that this intervention method is acceptable to most patients.  
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12 440           Regarding the components of the intervention that were considered helpful, most patients  
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15 441 reported that the explanation of the colorectal cancer screening process was helpful. Patients with  
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18 442 schizophrenia have barriers to accessing and understanding information about cancer screening and  
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21 443 those related to practical issues. [18-20] Moreover, many patients may not have been aware of the  
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24 444 information distributed by the municipality (i.e., the leaflet and brochure) or understood the procedure  
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27 445 to receive colorectal cancer screening. The present findings suggest that providing direct and  
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30 446 individualized explanations is effective in addressing these barriers.  
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#### 34 35 36 448 **4.2 Reasons for participation or non-participation in cancer screening**

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39 449 The largest proportion of patients stated that being encouraged in this study was the reason for  
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42 450 receiving cancer screening. This suggests that the CM intervention acted as an effective cue to undergo  
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45 451 cancer screening. This is consistent with a previous finding that physicians' recommendation of  
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48 452 screening is the strongest predictor of patients receiving cancer screening in those with psychiatric  
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51 453 disorders.[21] Furthermore, as other reasons for receiving screening, numerous patients highlighted  
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54 454 the desire for prevention/early detection of cancer and the low cost of cancer screening. This suggests  
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57 455 that the intervention was able to address the perceived benefits and barriers of patients with  
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6 456 schizophrenia. Few patients responded that fear of cancer was the reason for undergoing colorectal  
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9 457 cancer screening. This may be because the intervention did not emphasize the seriousness or severity  
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12 458 of cancer. In addition, a significant number of patients answered that they underwent cancer screening  
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15 459 because they had done so every year. Therefore, a simple intervention may be sufficient for such  
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18 460 patients. It is essential to encourage patients to undergo consistent colorectal cancer screening every  
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21 461 year.

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24 462 In a public opinion survey of the general population in Japan, the most common reason for  
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27 463 not receiving cancer screening is “lack of time.”[16] However, few patients who participated in the  
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30 464 present study cited lack of time or financial burden as reasons for not receiving cancer screening. In  
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33 465 our study participants, the most common reason for not undergoing colorectal cancer screening was  
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36 466 that it was bothersome, although the reasons why patients find cancer screening bothersome were not  
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39 467 clarified in our survey. In addition, several patients could not fully appreciate the significance of  
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42 468 screening or could not complete the procedure even after receiving the intervention. To overcome  
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45 469 barriers to colorectal cancer screening in these patients, implementing system-level measures to enable  
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48 470 the distribution of FOBT kits or conducting cancer screening at psychiatric hospitals may be effective.

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53 472 **4.3 Acceptability, appropriateness, and feasibility of the intervention from the providers’**  
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56 473 **perspective**

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59 474 The providers who provided the intervention evaluated it as an “acceptable” approach to encourage  
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6 475 participation in cancer screening at the psychiatric outpatient clinic. Supporting the physical health of  
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9 476 patients with mental illness was considered an important role of psychiatric outpatient clinics, and thus  
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12 477 awareness of this issue should be raised within clinics when implementing the intervention.  
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15 478 It was also perceived as “appropriate” to provide patients with tailored navigation on cancer  
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18 479 screening procedures. The CM intervention was considered appropriate because many patients  
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21 480 reported that they were able to complete the procedure themselves after receiving the individualized  
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24 481 intervention. Patient navigation has been gaining interest as an approach to reducing disparities in  
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27 482 cancer screening and diagnosis.[22] This was an essential component of the CM intervention.  
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30 483 In this study, providers perceived that it was easy to understand the content of and administer  
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33 484 the intervention. This suggests that it is likely to be “feasible” for implementing in routine clinical  
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36 485 practice. However, there are also challenges to the implementation of the intervention in a clinical  
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39 486 setting in terms of resources. In particular, providers considered it would be difficult to deliver the  
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42 487 intervention to all eligible patients simultaneously. There are currently insufficient outpatient staff to  
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45 488 provide interventions to the large number of outpatients who visit each day. Thus, it may be necessary  
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48 489 to adopt strategies according to the resources available at each facility, such as providing the  
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51 490 intervention initially to patients within reach and eventually to all individuals.  
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#### 54 492 **4.4 Limitations**

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58 493 First, the intervention was provided in only two hospitals. In addition, only three staff members with  
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6 494 long clinical experience participated in the interviews to evaluate the intervention. Because this study  
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9 495 was not conducted across different regions, differently sized psychiatric hospitals, or in staff with  
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12 496 varied experience, the generalizability of the results may be limited. Second, we only examined the  
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15 497 opinions of patients who had consented to participation in the RCT for cancer screening  
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18 498 encouragement. This may lead to an overestimation of acceptability from the patients' perspective due  
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21 499 to volunteer bias.[23] In addition, patients who did not participate in this study may have more severe  
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24 500 psychiatric symptoms than those who did participate, and the feasibility of administering interventions  
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26  
27 501 to such patients remains unknown. Third, for the interviews with providers, only three of the six  
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30 502 providers involved in the intervention participated. Therefore, the responses obtained in the present  
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33 503 study may not be representative of the opinions of the providers at the two facilities. Fourth, regarding  
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36 504 patient acceptability, we did not evaluate all seven components that comprise the theoretical  
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39 505 framework.[14]

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## 43 44 45 507 **5. CONCLUSION**

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48 508 The most essential component of the CM intervention according to patients was the in-person  
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51 509 counseling with an explanation of colorectal cancer screening by psychiatric care providers. From the  
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54 510 psychiatric care providers' perspective, the CM approach to encourage participation in colorectal  
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57 511 cancer screening was considered acceptable and appropriate. Although offering the intervention to all  
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6 512 patients eligible for cancer screening simultaneously may be difficult, the results indicated that the  
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9 513 intervention is easy to understand and administer. Further research, including the development of  
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12 514 educational methods for providers, is needed to implement this CM intervention in various psychiatric  
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15 515 clinical settings.  
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18 516

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51 527

54 528 **Contributors**

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7  
8  
9 531 the design of the study. MK, RS, TM1, YY2, and SH1 conducted the investigation. SH2 played a  
10  
11  
12 532 primary role in designing the statistical analysis. YY1, MF1, and TE conducted the qualitative analysis.  
13  
14  
15 533 TM2 played a primary role in designing the data management approach. YY1 and MF1 drafted the  
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17  
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#### 40 41 42 542 **Competing interests**

43  
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41  
42 560 authors have nothing to disclose.  
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45 561

48 562 **Patient consent for publication**

51 563 Not required.

54 564

57 565 **Ethics approval**

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6 566 This study was approved by the institutional ethics committee at the Okayama University Graduate  
7  
8  
9 567 School of Medicine, Dentistry, and Pharmaceutical Sciences and Okayama University Hospital on 23  
10  
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24 572 **Data sharing statement**

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26  
27 573 The datasets in this study are not publicly available because of the terms of consent to which the  
28  
29  
30 574 participants agreed but may be available from the corresponding author on reasonable request.  
31  
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36 576 **6. REFERENCES**

- 37  
38  
39 577 1. Crump C, Winkleby MA, Sundquist K, et al. Comorbidities and mortality in persons with  
40  
41  
42 578 schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170(3):324–33.  
43  
44  
45 579 <https://doi.org/10.1176/appi.ajp.2012.12050599>.  
46  
47  
48 580 2. Olfson M, Gerhard T, Huang C, et al. Premature mortality among adults with schizophrenia in  
49  
50  
51 581 the United States. *JAMA Psychiatry* 2015;72(12):1172–81.  
52  
53  
54 582 <https://doi.org/10.1001/jamapsychiatry.2015.1737>.  
55  
56  
57 583 3. Pettersson D, Gissler M, Hällgren J, et al. The overall and sex- and age-group specific incidence  
58  
59  
60

- 1  
2  
3  
4  
5  
6 584 rates of cancer in people with schizophrenia: a population-based cohort study. *Epidemiol*  
7  
8  
9 585 *Psychiatr Sci* 2020;29:e132. <https://doi.org/10.1017/S204579602000044X>.
- 10  
11  
12 586 4. Zhuo C, Tao R, Jiang R, et al. Cancer mortality in patients with schizophrenia: systematic review  
13  
14  
15 587 and meta-analysis. *Br J Psychiatry* 2017;211(1):7–13.  
16  
17  
18 588 <https://doi.org/10.1192/bjp.bp.116.195776>.
- 19  
20  
21 589 5. Hwang AR, Mangurian C. Improving breast cancer screening and care for women with severe  
22  
23  
24 590 mental illness. *J Clin Oncol* 2017;35(36):3996–8. <https://doi.org/10.1200/JCO.2017.76.0462>.
- 25  
26  
27 591 6. Solmi M, Firth J, Miola A, et al. Disparities in cancer screening in people with mental illness  
28  
29  
30 592 across the world versus the general population: prevalence and comparative meta-analysis  
31  
32  
33 593 including 4 717 839 people. *Lancet Psychiatry* 2020;7(1):52–63. <https://doi.org/10.1016/S2215->  
34  
35  
36 594 0366(19)30414-6.
- 37  
38  
39 595 7. Fujiwara M, Inagaki M, Nakaya N, et al. Cancer screening participation in schizophrenic  
40  
41  
42 596 outpatients and the influence of their functional disability on the screening rate: A cross-sectional  
43  
44  
45 597 study in Japan. *Psychiatry Clin Neurosci* 2017;71(12):813–25.  
46  
47  
48 598 <https://doi.org/10.1111/pcn.12554>.
- 49  
50  
51 599 8. Shin DW, Chang D, Jung JH, et al. Disparities in the participation rate of colorectal cancer  
52  
53  
54 600 screening by fecal occult blood test among people with disabilities: a national database study in  
55  
56  
57 601 South Korea. *Cancer Res Treat* 2020;52(1):60–73. <https://doi.org/10.4143/crt.2018.660>.
- 58  
59  
60

- 1  
2  
3  
4  
5  
6 602 9. Fujiwara M, Higuchi Y, Nakaya N, et al. Trends in cancer screening rates among individuals  
7  
8  
9 603 with serious psychological distress: an analysis of data from 2007 to 2016 Japanese national  
10  
11  
12 604 surveys, *J Psychosoc Oncol Res Pract* 2020;2(3):e025.  
13  
14  
15 605 <https://doi.org/10.1097/OR9.0000000000000025>  
16  
17  
18 606 10. Fujiwara M, Inagaki M, Shimazu T, et al. A randomised controlled trial of a case management  
19  
20  
21 607 approach to encourage participation in colorectal cancer screening for people with schizophrenia  
22  
23  
24 608 in psychiatric outpatient clinics: study protocol for the J-SUPPORT 1901 (ACCESS) study. *BMJ*  
25  
26  
27 609 *Open* 2019;9(11):e032955. <https://doi.org/10.1136/bmjopen-2019-032955>.  
28  
29  
30 610 11. Fujiwara M, Yamada Y, Shimazu T, et al. Encouraging participation in colorectal cancer  
31  
32  
33 611 screening for people with schizophrenia: a randomized controlled trial. *Acta Psychiatr Scand*  
34  
35  
36 612 2021;144(4):318–28. <https://doi.org/10.1111/acps.13348>.  
37  
38  
39 613 12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual  
40  
41  
42 614 distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*  
43  
44  
45 615 2011;38(2):65–76. <https://doi.org/10.1007/s10488-010-0319-7>.  
46  
47  
48 616 13. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-  
49  
50  
51 617 5. Washington, DC: American Psychiatric Association Publishing, 2013.  
52  
53  
54 618 14. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of  
55  
56  
57 619 reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17(1):88.  
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6 620 <https://doi.org/10.1186/s12913-017-2031-8>.
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9 621 15. Cabinet Office, Government of Japan, Public Opinion Survey on Cancer Control (in Japanese).  
10  
11  
12 622 <https://survey.gov-online.go.jp/h28/h28-gantaisaku/2-2.html> [Accessed 19 Oct 2021].  
13  
14  
15 623 16. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the health belief model.  
16  
17  
18 624 *Health Education Quarterly* 1988;15(2):175–83. <https://doi.org/10.1177/109019818801500203>  
19  
20  
21 625 17. Proctor EK, Landsverk J, Aarons G, et al. Implementation research in mental health services: an  
22  
23  
24 626 emerging science with conceptual, methodological, and training challenges. *Adm Policy Ment*  
25  
26  
27 627 *Health* 2009;36(1):24–34. <https://doi.org/10.1007/s10488-008-0197-4>.  
28  
29  
30 628 18. Irwin KE, Henderson DC, Knight HP, et al. Cancer care for individuals with schizophrenia.  
31  
32  
33 629 *Cancer* 2014;120(3):323–34. <https://doi.org/10.1002/cncr.28431>.  
34  
35  
36 630 19. Weinstein LC, Stefancic A, Cunningham AT, et al. Cancer screening, prevention, and treatment  
37  
38  
39 631 in people with mental illness. *CA Cancer J Clin* 2016;66(2):134–51.  
40  
41  
42 632 <https://doi.org/10.3322/caac.21334>.  
43  
44  
45 633 20. Clifton A, Burgess C, Clement S, et al. Influences on uptake of cancer screening in mental health  
46  
47  
48 634 service users: a qualitative study. *BMC Health Serv Res* 2016;16:257. <https://doi.org/10.1186/s12913-016-1505-4>.  
49  
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54 636 21. Friedman LC, Puryear LJ, Moore A, et al. Breast and colorectal cancer screening among low-  
55  
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57 637 income women with psychiatric disorders. *Psychooncology* 2005;14(9):786–91.  
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6 638 <https://doi.org/10.1002/pon.906>.

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9 639 22. Wells KJ, Battaglia TA, Dudley DJ, et al. Patient navigation: state of the art or is it science?

10  
11  
12 640 *Cancer* 2008;113(8):1999–2010. <https://doi.org/10.1002/cncr.23815>.

13  
14  
15 641 23. Tarquinio C, Kivits J, Minary L, et al. Evaluating complex interventions: perspectives and issues

16  
17  
18 642 for health behaviour change interventions. *Psychol Health* 2015;30(1):35–51.

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21 643 <https://doi.org/10.1080/08870446.2014.953530>.

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**Supplementary Table 1. Reasons for participation in cancer screening among the TAU group participants\***

		Patients in the TAU group who received cancer screening (N = 10)	
Categories	Patients' responses	N	%
Cue to action	Because it was encouraged in this study.	2	20.0
	Because it was encouraged by the primary psychiatrist.	0	0
	Because it was encouraged by my family physician.	2	20.0
	Because it was encouraged by my family.	0	0
	Because I received an invitation from the municipality.	0	0
	Because I had an upset stomach.	0	0
Perceived susceptibility	Because I was afraid of cancer.	0	0
	Because I had a family member with cancer.	1	10.0
	Because I had a friend with cancer.	0	0
	Because I had other physical illnesses.	0	0
Perceived benefit	Because I want to prevent cancer/detect cancer early.	2	20.0
Self-efficacy	Because I thought I could receive it.	0	0
Perceived barriers	Because it was not expensive.	1	10.0
	Because I found a clinic that was easy to visit.	0	0
Other	Because I receive cancer screening every year or sometimes.	6	60.0

\*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

Reasons for participation in cancer screening were classified by researchers into the following categories according to the Health Belief Model: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action, and self-efficacy.

Abbreviations: CM, case management; TAU, treatment as usual.

**Supplementary Table 2. Reasons for non-participation in cancer screening among the TAU group participants\***

Categories	Patients' responses	Patients in the TAU group who did not receive cancer screening (N = 65)	
		N	%
Perceived barriers	Because it was bothersome.	17	26.2
	Because I did not feel the necessity to receive it every year.	7	10.8
	Because there was no time.	9	13.8
	Because it was a financial burden.	2	3.1
	Because I had anxiety about having tests and being diagnosed with cancer.	1	1.5
	Because of obstacles to transport.	2	3.1
Perceived severity	Because I will visit a hospital when necessary.	11	16.9
Perceived susceptibility	Because I still have a long way to go before I get cancer.	2	3.1
Lack of knowledge	Because of the lack of knowledge about cancer screening.	5	7.7
Self-efficacy	Because I didn't feel like I could receive it.	2	3.1
Other	No particular reason.	4	6.2
<b>Content of free description**</b>			
Perceived barriers	Because of failure to receive cancer screening.	1	1.5
	Because of psychiatric symptoms.	3	4.6
Perceived severity	Because of the belief that cancer does not need to be detected/treated early.	3	4.6
Cue to action	Because I was not encouraged by my doctor to receive cancer screening.	2	3.1
	Because I recently had a colonoscopy.	2	3.1
Other	Because I was suspicious of this research.	0	0
	Because I failed to collect a stool specimen.	3	4.6

\*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

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6 \*\*For responses that did not fit predetermined options, the researchers coded the content of free  
7 descriptions and tabulated the number of responses.

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9 Reasons for non-participation in cancer screening were classified by researchers into the following  
10 categories according to the Health Belief Model: perceived susceptibility, perceived severity,  
11 perceived benefits, perceived barriers, cue to action, and self-efficacy.

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13 Abbreviations: CM, case management; TAU, treatment as usual.  
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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	p.1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	p.4, 5

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	p. 7, 8
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	p. 8

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	p. 8, 9
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	p. 14
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	p. 9-11
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	p. 9
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	p.8
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	p. 14, 15

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<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	p.13, 14
<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	p. 15, 16
<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	p. 14, 15
<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	p. 14, 15
<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	p. 13-15

### Results/findings

<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	p. 15-33
<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	p. 19-28

### Discussion

<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	p. 28-31
<b>Limitations</b> - Trustworthiness and limitations of findings	p. 31, 32

### Other

<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	p. 34, 35
<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	p. 34

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

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# BMJ Open

## Patients' acceptability and implementation outcomes of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia: a qualitative secondary analysis of a mixed-method randomized clinical trial

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Manuscript ID	bmjopen-2021-060621.R2
Article Type:	Original research
Date Submitted by the Author:	21-May-2022
Complete List of Authors:	<p>Yamada, Yuto; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Neuropsychiatry; Okayama University Hospital, Department of Neuropsychiatry  Fujiwara, Masaki; Okayama University Hospital, Department of Neuropsychiatry  Shimazu, Taichi; National Cancer Center, Division of Behavioral Sciences, Institute for Cancer Control  Etoh, Tsuyoshi; Shimane University Hospital, Department of Nursing  Kodama, Masafumi; Okayama Psychiatric Medical Center  So, Ryuhei ; Okayama Psychiatric Medical Center  Matsushita, Takanori; Zikei Hospital  Yoshimura, Yusaku; Zikei Hospital  Horii, Shigeo; Zikei Hospital  Fujimori, Maiko; National Cancer Center Institute for Cancer Control, Division of Supportive Care, Survivorship and Translational Research  Takahashi, Hirokazu ; National Cancer Center Institute for Cancer Control, Division of Screening Assessment and Management  Nakaya, Naoki; Tohoku University, Tohoku Medical Megabank Organization  Miyaji, Tempei; The University of Tokyo, Department of Clinical Trial Data Management, Graduate School of Medicine  Hinotsu, Shiro ; Sapporo Medical University, Department of Biostatistics and Data Management  Harada, Keita; Okayama University Hospital, Department of Gastroenterology  Okada, Hiroyuki; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Gastroenterology and Hepatology  Uchitomi , Yosuke; National Cancer Center Institute for Cancer Control, Group for Supportive Care and Survivorship Research  Yamada, Norihito; Okayama University Graduate School of Medicine Dentistry and Pharmaceutical Sciences, Department of Neuropsychiatry  Inagaki, Masatoshi; Shimane University, Department of Psychiatry, Faculty of Medicine</p>
<b>Primary Subject Heading</b>:	Mental health



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Secondary Subject Heading:	Oncology
Keywords:	Schizophrenia & psychotic disorders < PSYCHIATRY, QUALITATIVE RESEARCH, ONCOLOGY





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15 **4** analysis of a mixed-method randomized clinical trial  
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21 **6 Authors**

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24 **7** Yuto Yamada, MD<sup>1, 2</sup>, Masaki Fujiwara MD, PhD<sup>2\*</sup>, Taichi Shimazu, MD, PhD<sup>3</sup>, Tsuyoshi Etoh,  
25  
26  
27 **8** MS<sup>4</sup>, Masafumi Kodama, MD, PhD<sup>5</sup>, Ryuhei So, MD, MPH<sup>5</sup>, Takanori Matsushita, MD<sup>6</sup>, Yusaku  
28  
29  
30 **9** Yoshimura, MD, PhD<sup>6</sup>, Shigeo Horii, MD, PhD<sup>6</sup>, Maiko Fujimori, PhD<sup>7</sup>, Hirokazu Takahashi, MD,  
31  
32  
33 **10** PhD<sup>8</sup>, Naoki Nakaya, PhD<sup>9</sup>, Tempei Miyaji, MSc<sup>10, 11</sup>, Shiro Hinotsu, MD, PhD<sup>12</sup>, Keita Harada, MD,  
34  
35  
36 **11** PhD<sup>13</sup>, Hiroyuki Okada, MD, PhD<sup>14</sup>, Yosuke Uchitomi, MD, PhD<sup>15</sup>, Norihito Yamada, MD, PhD<sup>1</sup>,  
37  
38  
39 **12** Masatoshi Inagaki, MD, PhD<sup>16\*</sup>  
40  
41

42  
43  
44  
45 **14 Affiliations**

46  
47  
48 **15** <sup>1</sup>Department of Neuropsychiatry, Okayama University Graduate School of Medicine, Dentistry, and  
49  
50  
51 **16** Pharmaceutical Sciences, Okayama, Japan

52  
53  
54 **17** <sup>2</sup>Department of Neuropsychiatry, Okayama University Hospital, Okayama, Japan

55  
56  
57 **18** <sup>3</sup>Division of Behavioral Sciences, Institute for Cancer Control, National Cancer Center, Tokyo, Japan  
58  
59  
60

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5  
6  
7 19 <sup>4</sup>Department of Nursing, Shimane University Hospital, Izumo, Japan  
8  
9  
10 20 <sup>5</sup>Okayama Psychiatric Medical Center, Okayama, Japan  
11  
12  
13 21 <sup>6</sup>Zikei Hospital, Okayama, Japan  
14  
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16 22 <sup>7</sup>Division of Supportive Care, Survivorship and Translational Research, National Cancer Center  
17  
18 23 Institute for Cancer Control, Tokyo, Japan  
19  
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21 24 <sup>8</sup>Division of Screening Assessment and Management, National Cancer Center Institute for Cancer  
22  
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24 25 Control, Tokyo, Japan  
25  
26  
27 26 <sup>9</sup>Tohoku Medical Megabank Organization, Tohoku University, Sendai, Japan  
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30 27 <sup>10</sup>Department of Clinical Trial Data Management, Graduate School of Medicine, The University of  
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36 29 <sup>11</sup>Behavioral Sciences and Survivorship Research Group, Center for Public Health Sciences, National  
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42 31 <sup>12</sup>Department of Biostatistics and Data Management, Sapporo Medical University, Sapporo, Japan  
43  
44  
45 32 <sup>13</sup>Department of Gastroenterology, Okayama University Hospital, Okayama, Japan  
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54 35 <sup>15</sup>National Cancer Center Institute for Cancer Control, Group for Supportive Care and Survivorship  
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6 37 <sup>16</sup>Department of Psychiatry, Faculty of Medicine, Shimane University, Izumo, Japan  
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11  
12 39 **\*Correspondence**  
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14

15 40 Masaki Fujiwara, M.D., Ph.D.  
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17  
18 41 Department of Neuropsychiatry, Okayama University Hospital  
19

20  
21 42 2-5-1 Shikata-cho, Kita-ku, Okayama, Japan  
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23  
24 43 Tel: +81-86-235-7242  
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26  
27 44 E-mail: [mfujiwara@okayama-u.ac.jp](mailto:mfujiwara@okayama-u.ac.jp)  
28  
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30 45  
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33 46 Masatoshi Inagaki, M.D., Ph.D.  
34

35  
36 47 Department of Psychiatry, Faculty of Medicine, Shimane University  
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38  
39 48 89-1 Enya-cho, Izumo, Shimane 693-8501, Japan  
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41  
42 49 Tel: +81-853-20-2262  
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45 50 E-mail: [minagaki@med.shimane-u.ac.jp](mailto:minagaki@med.shimane-u.ac.jp)  
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6 **53 ABSTRACT (300 words)**  
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9 **54 Objectives**  
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12 55 We examined the efficacy of case management (CM) interventions to encourage participation in  
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15 56 colorectal cancer screening for schizophrenia patients. This study aimed to clarify patients'  
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30 **61 Study design and setting**  
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9 72 **Data collection and analysis**

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27 78 **Results**

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30 79 Forty-three of the 56 patients perceived that the intervention was acceptable. For the intervention  
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33 80 component, in-person counseling with an explanation of the screening process by psychiatric care  
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36 81 providers was most frequently reported as helpful by patients (48 of the 68 respondents). Psychiatric  
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39 82 care providers evaluated the intervention as acceptable, appropriate, and easy to understand and  
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42 83 administer. However, providing the intervention to all patients simultaneously was considered difficult  
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45 84 with the current human resources.  
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51 86 **Conclusions**

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54 87 This study showed that the CM intervention was perceived as acceptable by patients and acceptable  
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57 88 and appropriate by psychiatric care providers.  
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9 90 **Keywords**

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12 91 Cancer screening, schizophrenia, case management, patient navigation, mixed-method randomized  
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15 92 controlled trial  
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21 94 **Trial registration**

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24 95 UMIN000036017  
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30 97 **Strengths and limitations of the study**

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32 98 • This study was designed to incorporate a pre-planned qualitative study into a randomized  
33 99 controlled trial.  
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36 100 • Information related to the implementation of the intervention, as assessed by patients and  
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39 101 psychiatric care providers, was organized according to theoretical frameworks.  
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42 102 • Acceptability from the patients' perspective may be overestimated because we only examined  
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45 103 the opinions of patients who consented to the randomized controlled trial for cancer screening  
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48 104 encouragement.  
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51 105 • We did not investigate psychiatric hospitals of all sizes/regions, which limits the generalizability  
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54 106 of the present results.  
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6 108 **1. BACKGROUND**  
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9 109 Cancer is a leading cause of death among people with schizophrenia, and cancer mortality in those  
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12 110 with schizophrenia is greater than that in the general population.[1, 2] Delayed cancer detection is one  
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15 111 factor that contributes to the high cancer mortality rates in this population.[3,4] Therefore, there is a  
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18 112 crucial need to encourage guideline-recommended screening in patients with schizophrenia.[5]  
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21 113 A previous study showed disparities in cancer screening among people with  
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24 114 schizophrenia.[6, 7] Moreover, such disparities in cancer screening among people with a mental  
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27 115 illness have persisted or become even wider.[8, 9] Therefore, we developed a case management  
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30 116 (CM) approach to encourage participation in cancer screening, with a particular focus on colorectal  
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33 117 cancer screening using a fecal occult blood test (FOBT), for patients with schizophrenia in  
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36 118 psychiatric outpatient clinics.[10] In psychiatric medical settings, CM, which includes the planning  
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39 119 and coordinating of necessary services for community life, is commonly implemented. CM may also  
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42 120 include advice on maintaining physical health and referral to appropriate specialists. The present  
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45 121 intervention provided education and navigation regarding cancer screening as a part of CM in daily  
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48 122 clinical practice.  
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51 123 The efficacy of this intervention has been confirmed by a randomized controlled trial  
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54 124 (RCT).[11] For the next step, it is necessary to confirm the effectiveness of this intervention in  
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57 125 routine clinical settings. However, to implement a new intervention in routine clinical practice, it is  
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6 126 valuable to determine patients' acceptability of the intervention and identify components of the  
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9 127 intervention that patients perceive as helpful. This is because the intervention is complex and  
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12 128 includes personal education and navigation for cancer screening. Furthermore, it is necessary to  
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15 129 examine implementation outcomes, such as acceptability, appropriateness, and feasibility,[12] as  
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18 130 perceived by psychiatric care providers.  
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21 131 During this trial, we conducted a pre-planned qualitative study to determine the information  
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24 132 needed to carry out future implementation research. In this qualitative study, we first aimed to evaluate  
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27 133 patients' acceptability of the intervention, identify helpful components of the intervention, and explore  
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30 134 the reasons for participation or non-participation in cancer screening. Second, we examined the  
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33 135 acceptability, appropriateness, and feasibility of the intervention as assessed by psychiatric care  
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36 136 providers.  
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## 40 41 42 138 **2. METHODS**

### 43 44 45 139 **2.1 Study design and participants**

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48 140 This study was a secondary analysis of a mixed-method RCT that evaluated the efficacy of the CM  
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51 141 approach to encourage participation in cancer screening for people with schizophrenia. In this RCT,  
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54 142 we interviewed study participants and psychiatric care providers who administered the intervention.  
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57 143 All participants provided written informed consent prior to enrollment. This study is registered in the  
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6 144 UMIN Clinical Trials Registry (UMIN000036017). The protocol of the trial, details of the intervention,  
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9 145 and main trial findings were reported elsewhere.[10, 11] Therefore, the method of the trial is described  
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12 146 briefly.

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15 147 We recruited patients from two psychiatric outpatient clinics in Okayama City in Japan: the  
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18 148 Okayama Psychiatric Medical Center (252 beds and approximately 250 outpatient visits per day) and  
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21 149 Zikei Hospital (570 beds and approximately 160 outpatient visits per day). Eligible participants were  
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24 150 aged  $\geq 40$  years in the 2019 fiscal year; had visited the recruitment sites as their primary psychiatric  
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27 151 outpatient service; and were outpatients diagnosed by their current primary psychiatrist with  
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30 152 schizophrenia or schizoaffective disorder, according to the Diagnostic and Statistical Manual of  
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33 153 Mental Disorders, Fifth Edition.[13] Key exclusion criteria were patients with a history of colorectal  
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36 154 cancer; those living in an institution where residents were supported in receiving cancer screening;  
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39 155 and patients judged to be at risk of symptom worsening by participating in the study.

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42 156 Patients were randomly assigned to receive usual intervention, which included municipal  
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45 157 public education (treatment as usual: TAU group), or an intervention to encourage participation in  
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48 158 cancer screening using CM plus TAU (CM plus TAU group).

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## 52 53 54 160 **2.2 Cancer screening program provided by the municipality**

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57 161 In Japan, the Ministry of Health, Labour and Welfare (MHLW) recommends population-based cancer  
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6 162 screening for colorectal, gastric, lung, breast, and cervical cancer. These screenings are provided by  
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9 163 local governments with a low co-payment. In this study, we recommended colorectal cancer screening  
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12 164 using the FOBT for individuals aged 40 years and older. The cancer screening program of Okayama  
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15 165 City does not mail the FOBT kit in advance. Instead, individuals select a clinic offering cancer  
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18 166 screening and make an appointment to visit the clinic to receive the kit. Although individuals with a  
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21 167 low household income can receive free screening, eligible individuals must apply for a coupon in  
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24 168 advance at the municipal office.  
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27 169 The Okayama municipal government distributes a leaflet and detailed brochure encouraging  
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30 170 participation in the above cancer screening program to all households in the city once a year.  
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### 34 35 36 172 **2.3 Case management intervention to encourage participation in cancer screening**

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39 173 A case manager (nurse or psychiatric social worker) provided three counseling sessions to the study  
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42 174 participants allocated to the CM plus TAU group. The CM intervention aimed to educate and navigate  
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45 175 patients around colorectal cancer screening.  
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48 176 The first session, which was conducted in person, comprised the following components: a)  
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51 177 education on the importance and content of colorectal cancer screening, using a pamphlet, b)  
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54 178 assistance in making decisions and an appointment for colorectal cancer screening, and c) assistance  
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57 179 in obtaining a coupon for free screening, if necessary. Other cancer screening was also briefly  
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6 180 mentioned using the pamphlet. Education on cancer screening using the pamphlet did not take the  
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9 181 approach whereby the seriousness or severity of cancer was emphasized.

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12 182 After the first in-person session, a case manager provided at least two follow-up in-person  
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15 183 or telephone counseling sessions to remind or support the patient's participation in cancer screening.  
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18 184 The follow-up session could be skipped if the subject was judged to be able to receive cancer screening  
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21 185 without the follow-up sessions. This judgment was made by case managers according to their clinical  
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24 186 assessment of the patient's functioning.

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27 187 This intervention was standardized in the form of a manual. Psychiatric nurses or social  
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30 188 workers who had already worked at the study sites administered the intervention as case managers,  
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33 189 according to the procedures described in the manual. The intervention was administered during  
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36 190 patients' outpatient visits. In Japan, the MHLW requires that primary care physicians encourage their  
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39 191 patients to undergo cancer screening. The present intervention is consistent with the national policy  
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42 192 for cancer screening.

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#### 46 47 48 194 **2.4 Follow-up interview conducted after the end of the intervention period**

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51 195 After the end of the municipal cancer screening period, qualitative follow-up interviews were  
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54 196 conducted with both case managers and study participants between January 2020 and March 2020.

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6 198 **2.4.1 Interviews with patients**  
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9 199 In a structured interview, the case manager asked the CM plus TAU group participants about “patients’  
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12 200 acceptability of the intervention,” “helpful components of the intervention,” and “reasons for  
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15 201 participation or non-participation in cancer screening.”  
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18 202 *For patients’ acceptability of the intervention*, patients were asked about “affective attitude,”  
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20  
21 203 which is one of the components of the theoretical framework of acceptability.[14] This theoretical  
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23  
24 204 framework was developed according to the overview of systematic reviews focusing on patients’  
25  
26  
27 205 acceptability of healthcare interventions.[14] We selected the affective attitude that was considered  
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29  
30 206 most helpful in disseminating the intervention. Patients were asked, “how do you feel about this  
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33 207 recommendation for cancer screening?”  
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36 208 *For helpful components of the intervention*, patients were asked to describe the components  
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39 209 of the intervention that they perceived as helpful. The interviewer categorized patients’ open-ended  
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42 210 responses into the following components of the intervention: assignment of a case manager;  
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45 211 explanation of colorectal cancer screening; explanation of the coupon for free screening; planning a  
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48 212 schedule for the cancer screening; and follow-up contact at a later date. Patients were asked, “what  
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51 213 was helpful in this intervention?”  
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54 214 *For reasons for participation or non-participation in cancer screening*, patients were asked  
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57 215 to describe their reasons for participation or non-participation with an open-ended question. The  
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6 216 interviewers categorized patients' responses into predetermined options, which were based on a  
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9 217 Japanese public opinion survey on cancer control,[15] and were classified into the following categories  
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12 218 based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits;  
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15 219 perceived barriers; cue to action; and self-efficacy.[16] Patients were asked, "what were your reasons  
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18 220 for participating or not participating in colorectal cancer screening?"  
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21 221 The interviewer summarized the content immediately after the responses were obtained, and  
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23  
24 222 the interviews with patients were not recorded.  
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#### 28 29 30 224 **2.4.2 Interviews with providers**

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33 225 A group interview was conducted with providers to assess the implementation outcomes of the  
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36 226 intervention. Proctor et al. proposed the Implementation Outcomes Framework,[17] which  
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39 227 conceptualizes the variables of interest in implementation evaluation. Among the implementation  
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42 228 outcomes included in this framework, we investigated "acceptability," "appropriateness," and  
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45 229 "feasibility," which were all measurable factors in this study.  
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48 230 *Acceptability* is defined as the perception among providers that an intervention is agreeable,  
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51 231 palatable, or satisfactory.[12] For "acceptability," providers were asked, "what do you think about this  
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54 232 intervention in terms of whether it is an agreeable, palatable, or satisfactory intervention?"  
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57 233 *Appropriateness* is defined as the perceived fit, relevance, or compatibility of the  
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6 234 intervention for providers.[12] In this study, providers were asked, “did this intervention meet the  
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9 235 objective of improving cancer screening uptake among people with schizophrenia?” and “were the  
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12 236 components of the intervention fit for purpose to make the intervention effective?”  
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15 237 *Feasibility* is defined as the extent to which an intervention can be successfully used or  
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18 238 carried out within a given setting.[12] In this study, providers were asked, “would this intervention be  
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21 239 feasible to implement in a routine psychiatric outpatient setting?”  
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24 240 Two case managers who administered the intervention and a psychiatrist who was involved  
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27 241 in the recruitment of the subjects participated in this study. One researcher (M.F1., a psychiatrist with  
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30 242 14 years of clinical experience) acted as the interviewer and facilitated discussions on the  
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33 243 “acceptability,” “appropriateness,” and “feasibility” of the intervention.[11] The interview was  
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36 244 recorded, and a verbatim transcript was produced.  
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## 40 41 42 246 **2.5 Data analysis**

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45 247 For the analysis of patient responses, those whose self-reports of receiving colorectal cancer screening  
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48 248 did not match the municipal records of the screening were excluded from the analysis to improve the  
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51 249 validity of the results. For “patients’ acceptability of the intervention,” content analysis was performed  
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54 250 on the patients’ responses described by interviewers. The open-ended responses were coded following  
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57 251 a discussion between two researchers (YY, a psychiatrist with 6 years of clinical experience, and TE,  
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6 252 a nurse with more than 10 years of clinical experience), and the number of responses was tabulated  
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9 253 according to the codes created. For “helpful components of the intervention,” “reasons for  
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12 254 participation in cancer screening,” and “reasons for non-participation in cancer screening,” the open-  
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15 255 ended responses obtained from the interviews were categorized into predetermined options by the  
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18 256 interviewers. Answers that did not fit into the predetermined options were coded by the same  
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21 257 researchers, and the number of responses was tabulated according to the codes created. Responses to  
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24 258 “patients’ acceptability of the intervention” and “helpful components of the intervention” were  
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27 259 stratified according to whether patients had received cancer screening.

30 260 For the data obtained from the interviews with providers, the researcher extracted and  
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33 261 summarized the opinions obtained from the verbatim transcripts and asked the interviewees to revise  
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36 262 and confirm the summarized descriptions.  
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## 42 264 **2.6 Patient and public involvement statement**

45 265 Patients were not directly involved in the development of the research questions and interventions or  
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48 266 in the design of the planned study. We obtained patients’ feedback regarding the intervention in this  
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51 267 study. The results of the study will be published on our facilities’ and funder’s website.  
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## 57 269 **3. RESULTS**

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6 270 **3.1 Patient enrollment and baseline characteristics**  
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9 271 Between June 3, 2019, and September 9, 2019, 172 eligible participants were randomly assigned to  
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12 272 either the CM plus TAU group (n = 86) or the TAU group (n = 86). Eighty participants in the CM plus  
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15 273 TAU group (94.1%) and 83 participants in the TAU group (97.6%) took part in the follow-up  
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18 274 interview. Of these, self-reports on whether they had received colorectal cancer screening were  
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21 275 consistent with the results of the inquiry by Okayama City in 78 participants in the CM plus TAU  
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24 276 group and 75 participants in the TAU group. There were inconsistencies between the self-reported  
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27 277 results and the city's records for two participants in the CM plus TAU group and eight participants in  
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29  
30 278 the TAU group. The background information of the included 153 participants is shown in Table 1.  
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32  
33 279 Thirty-nine participants (50.0%) in the CM plus TAU group and one participant (10.0%) in the TAU  
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35  
36 280 group received cancer screening. Of these, seven participants in the CM plus TAU group and one in  
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39 281 the TAU group required detailed examinations, such as colonoscopy, and all of these participants  
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42 282 reported that they had undergone the prescribed detailed examination.  
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285 **Table 1. Patient characteristics**

	Case management intervention plus treatment as usual (N = 78)	Treatment as usual (N = 75)	Total (N = 153)
<b>Age, years</b>			
Median (range)	52 (39, 74)	54 (39, 80)	53 (39, 80)
<b>Sex</b>			
Women	37 (47.4%)	35 (46.7%)	72 (47.1%)
<b>Educational level*</b>			
≤ Junior high school	18 (23.1%)	15 (20.0%)	31 (20.3%)
> Junior high school but ≤ high school	36 (46.2%)	38 (50.7%)	74 (48.4%)
> High school but ≤ junior/vocational college	8 (10.3%)	9 (12.0%)	17 (11.1%)
≥ University or college	16 (20.5%)	13 (17.3%)	29 (19.0%)
<b>Marital status*</b>			
Married	9 (11.5%)	8 (10.7%)	17 (11.1%)
<b>Living alone*</b>			
Yes	39 (50.0%)	36 (48.0%)	75 (49.0%)
<b>Current outpatient for physical illness*</b>			
Yes	38 (48.7%)	35 (46.7%)	73 (47.7%)
<b>History of receiving colorectal cancer screening*</b>			
Yes	35 (44.9%)	30 (40.0%)	65 (42.5%)
No	43 (55.1%)	44 (58.7%)	87 (56.9%)
Unknown	0 (0%)	1 (1.3%)	1 (0.7%)
<b>mGAF score</b>			
Mean (SD)	49.6 (15.7)	50.9 (14.8)	50.2 (15.2)
Range	15, 85	25, 85	15, 85
<b>Participation in colorectal cancer screening</b>			
Received colorectal cancer screening	39 (50.0%)	10 (13.3%)	49 (32.0)
Needed a detailed examination*	7 (17.9%)	1 (10.0%)	8 (16.3%)
Received a detailed examination*	7 (100%)	1 (100%)	8 (100%)
Results of detailed examination*			
A polyp was detected and resected	3 (42.9%)	0 (0%)	3 (37.5%)
Hemorrhoid	1 (14.3%)	0 (0%)	1 (12.5%)
Enteritis	1 (14.3%)	0 (0%)	1 (12.5%)
No abnormal findings	2 (28.6%)	1 (0%)	3 (37.5%)

286 \*Self-reported.

287 Abbreviations: mGAF, modified global assessment of functioning; SD, standard deviation.

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289 **3.2 Patients' acceptability and helpful components of the intervention**

290 Table 2 shows the responses obtained from patients regarding their impressions of the intervention.

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6 291 Of the 78 patients in the CM plus TAU group, 56 responded, of whom 30 received colorectal cancer

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9 292 screening and 26 did not.

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For peer review only

295 **Table 2. Patients' acceptability of the intervention\***

	<b>Patients of CM plus TAU group who responded</b>	
	<b>Uptake of colorectal cancer screening</b>	
	<b>Yes (N = 30)</b>	<b>No (N = 26)</b>
I was satisfied with the encouragement.	29	14
It was very good.	14	4
It was a good opportunity to receive cancer screening.	9	0
The explanations of cancer screening and the screening procedure were helpful.	3	4
I am glad that the polyp was treated quickly.	2	0
I would like this recommendation to be continued.	1	0
I felt it was important to have cancer screening.	1	6
It was not uncomfortable to be encouraged.	-†	1
I felt I did not need to undergo the screening right now.	-†	9
I felt it was bothersome.	1	1
I felt suspicious when they said "research."	-†	1

296 \*Multiple answers allowed. Patients were asked to provide open-ended responses. Content analysis  
 297 was performed by the researchers, and the number of responses was tabulated according to the codes  
 298 created.

299 †No responses on this content were obtained. Patients were not asked their opinion on this content in  
 300 a close-ended question.

301 Abbreviations: CM, case management; TAU, treatment as usual.

302 Of the 39 patients in the CM plus TAU group who received colorectal cancer screening, 30 (76.9%)  
 303 responded. Of the 39 patients in CM plus TAU group who did not receive screening, 26 (66.7%)  
 304 responded.

305 One patient provided multiple responses, stating that "the explanation of cancer screening and the  
 306 screening procedure were helpful" and "I would like this recommendation to be continued."

307

308 Of the 30 patients who underwent colorectal cancer screening, 29 reported that they were

309 satisfied with the encouragement. Specifically, the following comments were made by participants:

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6 310 *“It was very good, please continue next year.” ID 111*

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9 311 *“I am glad that a polyp was found and treated quickly.” ID 136*

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12 312 Of the 26 patients who did not undergo cancer screening, 14 said they were satisfied with  
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15 313 the encouragement. In addition, one patient voluntarily stated that they did not consider it  
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18 314 uncomfortable to be encouraged. However, of the patients who did not undergo cancer screening, nine  
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21 315 responded that they felt they did not need to undergo screening at the time. Specifically, the following  
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24 316 comments were obtained:

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27 317 *“It’s not necessary for me, so it doesn’t matter if you explain it to me.” ID 55*

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30 318 Table 3 shows the responses from patients regarding the components of the intervention  
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33 319 which were considered helpful. Among the patients in the CM plus TAU group who underwent cancer  
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36 320 screening, the most common response was “explanation of colorectal cancer screening,” which was  
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39 321 deemed helpful by 31 (81.6%) patients. This was followed by “assignment of a case manager” and  
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42 322 “explanation of the coupon for free screening,” which were considered helpful by 19 (50.0%) and 17  
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45 323 (47.4%) patients, respectively.

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326 **Table 3. Helpful components of the intervention\***

	Patients of the CM plus TAU group who responded (N = 68)			
	Uptake of colorectal cancer screening			
	Yes (N = 38)		No (N = 30)	
	N	%	N	%
Assignment of a case manager	19	50.0	8	26.7
Explanation of colorectal cancer screening	31	81.6	17	56.7
Explanation of the coupon for free screening	17	47.4	10	33.3
Planning a schedule for the cancer screening	4	13.2	2	6.7
Follow-up contact at a later date	15	39.5	5	16.7
No helpful points	5	10.5	8	23.3

327 \*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into  
 328 predetermined options by the interviewers, and the number of responses was tabulated.

329 Abbreviations: CM, case management; TAU, treatment as usual.

330 Of the 39 patients who received colorectal cancer screening in the CM plus TAU group, 38 (97.4%)  
 331 responded. Of the 39 patients who did not receive colorectal cancer screening in the CM plus TAU  
 332 group, 30 (76.9%) responded.

333

### 334 3.3 Reasons for participation or non-participation in cancer screening

335 Table 4 shows the responses obtained from patients regarding their reasons for undergoing colorectal  
 336 cancer screening. The most common response was “because it was encouraged in this study,” which  
 337 was the response of 22 (56.4%) patients. The second most common reason was “because I want to  
 338 prevent cancer/detect cancer early,” which was the response of 16 patients (41.0%). Seven patients

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6 339 (17.9%) answered “because I am afraid of cancer.”  
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For peer review only



340 **Table 4. Reasons for participation in cancer screening\***

Categories	Patients' responses	Patients in CM plus TAU group who received cancer screening (N = 39)	
		N	%
Cue to action	Because it was encouraged in this study.	22	56.4
	Because it was encouraged by the primary psychiatrist.	7	17.9
	Because it was encouraged by my family physician.	1	2.6
	Because it was encouraged by my family.	0	0
	Because I received an invitation from the municipality.	1	2.6
	Because I had an upset stomach.	3	7.7
Perceived susceptibility	Because I was afraid of cancer.	7	17.9
	Because I had a family member with cancer.	4	10.3
	Because I had a friend with cancer.	1	2.6
Perceived benefit	Because I had other physical illnesses.	3	7.7
	Because I want to prevent cancer/detect cancer early.	16	41.0
Self-efficacy	Because I thought I could receive it.	5	12.8
Perceived barriers	Because it was not expensive.	15	38.5
	Because I found a clinic that was easy to visit.	6	15.4
Other	Because I receive cancer screening every year or sometimes.	14	35.9

341 \*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into  
342 predetermined options by the interviewers, and the number of responses was tabulated.

343 Reasons for participation in cancer screening were classified by researchers into the following  
344 categories based on the Health Belief Model: perceived susceptibility; perceived severity; perceived  
345 benefits; perceived barriers; cue to action; and self-efficacy.

346 Reasons for participation in cancer screening among the TAU group participants are shown in  
347 Supplementary Table 1.

348 Abbreviations: CM, case management; TAU, treatment as usual.

349

350 Table 5 shows the responses of patients regarding the reasons for not receiving cancer  
351 screening. The most common reason for not receiving cancer screening was "because it was  
352 bothersome," given by 13 (33.3%) patients. Other common reasons were "I will visit a hospital when

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6 353 necessary” and “lack of knowledge about screening,” which were given by seven (17.9%) and five  
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9 354 (12.8%) patients, respectively. For “lack of knowledge about cancer screening,” patients made the  
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12 355 following comments:

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15 356 *“I didn’t receive it because I have good bowel movements.” ID 67*

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18 357 *“I didn’t receive it because I had already had the screening before, and I thought I didn’t*  
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21 358 *need to take it again.” ID 160*

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24 359 Four patients (10.3%) provided the reason, “failure to receive cancer screening” and made the  
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27 360 following comments:

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30 361 *“I misunderstood the period during which the screening was conducted.” ID 75*

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33 362 *“I was going to see the doctor, but I forgot my coupon for free screening.” ID 4*

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365 **Table 5. Reasons for non-participation in cancer screening\***

Categories	Patients' responses	Patients in the CM plus TAU group who did not receive cancer screening (N = 39)	
		N	%
Perceived barriers	Because it was bothersome.	13	33.3
	Because I did not feel the necessity to receive it every year.	5	12.8
	Because there was no time.	1	2.6
	Because it was a financial burden.	1	2.6
	Because I had anxiety about having tests and being diagnosed with cancer.	1	2.6
	Because of obstacles to transport.	0	0
Perceived severity	Because I will visit a hospital when necessary.	7	17.9
Perceived susceptibility	Because I still have a long way to go before I get cancer.	1	2.6
Lack of knowledge	Because of the lack of knowledge about cancer screening.	2	5.1
Self-efficacy	Because I didn't feel like I could receive it.	0	0
Other	No particular reason.	1	2.6
<b>Content of free description**</b>			
Perceived barriers	Because of failure to receive cancer screening.	4	10.3
	Because of psychiatric symptoms.	4	10.3
Perceived severity	Because of the belief that cancer does not need to be detected/treated early.	1	2.6
Other	Because I recently had a colonoscopy.	2	5.1
	Because I was suspicious of this research.	1	2.6

366 \*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into  
 367 predetermined options by the interviewers, and the number of responses was tabulated.

368 \*\*For responses that did not fit the predetermined options, researchers coded the content as free  
 369 description and tabulated the number of responses.

370 Reasons for non-participation in cancer screening were classified by researchers into the following  
 371 categories based on the Health Belief Model: perceived susceptibility; perceived severity; perceived  
 372 benefits; perceived barriers; cue to action; and self-efficacy.

373 Reasons for non-participation in cancer screening among the TAU group participants are shown in  
 374 Supplementary Table 2.

375 Abbreviations: CM, case management; TAU, treatment as usual.

376

377 **3.4 Acceptability, appropriateness, and feasibility of the intervention from the providers'**  
 378 **perspective**

379 The group interviews were conducted with three of the six providers who were involved in the  
 380 intervention. The providers' backgrounds were a nurse with 20 years of clinical experience, a  
 381 psychiatric social worker with 25 years of clinical experience and a psychiatrist with 11 years of  
 382 clinical experience. The implementation outcomes of "acceptability," "appropriateness," and  
 383 "feasibility" as assessed by the providers are summarized in Table 6.

384

385 **Table 6. Acceptability, appropriateness, and feasibility of the intervention from the providers'**  
 386 **perspective**

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 Acceptability
 

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- It is an acceptable intervention for psychiatric clinics to provide encouragement.
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 Appropriateness
 

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- Maintaining patients' physical health is one of the roles of psychiatric clinics.
  - This intervention, which provides explanations and support tailored to each patient, is suited to the aim of enabling people with severe mental illness to have access to cancer screening.
  - It is worthwhile to encourage and explain cancer screening in person, rather than only providing materials to encourage screening.
  - It is important to explain to patients about the coupon for free screening. Some patients decided to receive screening after discovering it was available for free or at a low cost.
  - Most patients were able to make an appointment with the hospital to receive cancer screening by themselves; thus, this intervention was appropriate.
  - It is essential that the case manager and the patient choose which hospital to receive cancer screening together.
  - Few patients changed their intentions of receiving/not receiving cancer screening during the follow-up session. Therefore, follow-up sessions may not be necessary for all patients.
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 Feasibility
 

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- The intervention does not require time-consuming training sessions. Once explained, it is possible to administer the intervention in accordance with the procedures.
  - The intervention procedure could be conducted in routine clinical practice.
  - The intervention could be administered quickly for patients who have a family physician or a history of receiving cancer screening. As the number of those who have undergone cancer screening increases, the burden on case managers will reduce.
  - It is difficult to encourage all patients eligible for colorectal cancer screening simultaneously because of limited resources. The impact of the COVID-19 epidemic introduced further difficulties.
  - It is difficult to conduct follow-up sessions with the same staff member.
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Regarding “acceptability,” the following comments were made:

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*“There are many patients who think they should receive cancer screening but do not because they did not know much about cancer screening. It is an acceptable intervention for psychiatric clinics to provide encouragement that is tailored to the patient’s functional capabilities.” Psychiatric social worker, 25 years of clinical experience*

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Regarding “appropriateness,” the following comments were made:

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*“Maintaining patients’ physical health is one of the roles of psychiatric clinics.” Psychiatrist, 11 years of clinical experience*

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*“It is worthwhile to encourage and explain screening in person. Many patients may not receive screening if they are only given materials to encourage screening.” Nurse, 20 years of clinical experience*

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*“It is important to explain about the coupon for free screening. Some patients decided*

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6 401 *to receive screening after realizing that it was available for free or at a low cost.”*

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9 402 *Nurse, 20 years of clinical experience*

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12 403 *“Many patients were able to go through the process on their own after receiving the*

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15 404 *explanation. It is an appropriate intervention.” Psychiatric social worker, 25 years of*

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18 405 *clinical experience*

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20 406 *“During the follow-up sessions, few patients changed their intentions of receiving/not*

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23 407 *receiving cancer screening or required additional support. Follow-up sessions may not*

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25 408 *be necessary for all patients.” Psychiatric social worker, 25 years of clinical*

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28 409 *experience*

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30 410 In terms of “feasibility,” the following comments were made:

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32 411 *“This intervention will take some getting used to but will not require time-consuming*

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34 412 *training sessions. Once explained, it is possible to carry out the intervention in*

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36 413 *accordance with the procedures.” Psychiatric social worker, 25 years of clinical*

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38 414 *experience*

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40 415 *“This intervention could be administered quickly for patients who have a history of*

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42 416 *undergoing cancer screening. As the number of those who have undergone cancer*

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44 417 *screening increases, the burden on case managers will be reduced.” Psychiatric social*

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46 418 *worker, 25 years of clinical experience*

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6 419 *“It is difficult to encourage all eligible patients for colorectal cancer screening at once*  
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9 420 *in terms of human resources. The impact of the COVID-19 epidemic made it even more*  
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12 421 *difficult.” Nurse, 20 years of clinical experience*  
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17 424 **4. DISCUSSION**

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24 425 In this study, the CM intervention was evaluated as acceptable by patients. In-person counseling with  
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27 426 an explanation of cancer screening by psychiatric care providers was the most common reason for  
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30 427 receiving cancer screening. From the providers’ perspective, the intervention delivered in a psychiatric  
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33 428 outpatient setting was perceived as “acceptable” and “appropriate.” As was intended when the  
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36 429 intervention was developed, the intervention was simple for providers to understand and administer.  
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39 430 However, it was difficult to provide the intervention to all patients simultaneously, which presents a  
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42 431 challenge for its implementation in routine clinical practice. The results of this study may help  
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45 432 implement the CM intervention to encourage participation in colorectal cancer screening in clinical  
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51 435 **4.1 Patients’ acceptability and helpful components of the intervention**

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57 436 From the patients’ perspective, evaluations of the intervention were mostly positive, which suggested  
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6 437 that there is patient demand for this intervention. In addition, few patients, including those who did  
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9 438 not receive colorectal cancer screening, reported any discomfort or anxiety about receiving the  
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12 439 intervention. This suggests that this intervention method is acceptable to most patients.  
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15 440 Regarding the components of the intervention that were considered helpful, most patients  
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18 441 reported that the explanation of the colorectal cancer screening process was helpful. Patients with  
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21 442 schizophrenia have barriers to accessing and understanding information about cancer screening and  
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24 443 those related to practical issues. [18-20] Moreover, many patients may not have been aware of the  
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27 444 information distributed by the municipality (i.e., the leaflet and brochure) or understood the procedure  
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30 445 to receive colorectal cancer screening. The present findings suggest that providing direct and  
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33 446 individualized explanations is effective in addressing these barriers.  
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#### 37 38 39 448 **4.2 Reasons for participation or non-participation in cancer screening**

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42 449 The largest proportion of patients stated that being encouraged in this study was the reason for  
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45 450 receiving cancer screening. This suggests that the CM intervention acted as an effective cue to undergo  
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48 451 cancer screening. This is consistent with a previous finding that physicians' recommendation of  
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51 452 screening is the strongest predictor of patients receiving cancer screening in those with psychiatric  
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54 453 disorders.[21] Furthermore, as other reasons for receiving screening, numerous patients highlighted  
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57 454 the desire for prevention/early detection of cancer and the low cost of cancer screening. This suggests  
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6 455 that the intervention was able to address the perceived benefits and barriers of patients with  
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9 456 schizophrenia. Few patients responded that fear of cancer was the reason for undergoing colorectal  
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12 457 cancer screening. This may be because the intervention did not emphasize the seriousness or severity  
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15 458 of cancer. In addition, a significant number of patients answered that they underwent cancer screening  
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18 459 because they had done so every year. Therefore, a simple intervention may be sufficient for such  
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21 460 patients. It is essential to encourage patients to undergo consistent colorectal cancer screening every  
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24 461 year.

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27 462 In a public opinion survey of the general population in Japan, the most common reason for  
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30 463 not receiving cancer screening is “lack of time.”[16] However, few patients who participated in the  
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33 464 present study cited lack of time or financial burden as reasons for not receiving cancer screening. In  
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36 465 our study participants, the most common reason for not undergoing colorectal cancer screening was  
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39 466 that it was bothersome, although the reasons why patients find cancer screening bothersome were not  
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42 467 clarified in our survey. In addition, several patients could not fully appreciate the significance of  
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45 468 screening or could not complete the procedure even after receiving the intervention. To overcome  
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48 469 barriers to colorectal cancer screening in these patients, implementing system-level measures to enable  
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51 470 the distribution of FOBT kits or conducting cancer screening at psychiatric hospitals may be effective.

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57 472 **4.3 Acceptability, appropriateness, and feasibility of the intervention from the providers’**  
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6 473 **perspective**  
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9 474 The providers who provided the intervention evaluated it as an “acceptable” approach to encourage  
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12 475 participation in cancer screening at the psychiatric outpatient clinic. Supporting the physical health of  
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15 476 patients with mental illness was considered an important role of psychiatric outpatient clinics, and thus  
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18 477 awareness of this issue should be raised within clinics when implementing the intervention.  
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21 478 It was also perceived as “appropriate” to provide patients with tailored navigation on cancer  
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24 479 screening procedures. The CM intervention was considered appropriate because many patients  
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27 480 reported that they were able to complete the procedure themselves after receiving the individualized  
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30 481 intervention. Patient navigation has been gaining interest as an approach to reducing disparities in  
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33 482 cancer screening and diagnosis.[22] This was an essential component of the CM intervention.  
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36 483 In this study, providers perceived that it was easy to understand the content of and administer  
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39 484 the intervention. This suggests that it is likely to be “feasible” for implementing in routine clinical  
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42 485 practice. However, there are also challenges to the implementation of the intervention in a clinical  
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45 486 setting in terms of resources. In particular, providers considered it would be difficult to deliver the  
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48 487 intervention to all eligible patients simultaneously. There are currently insufficient outpatient staff to  
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51 488 provide interventions to the large number of outpatients who visit each day. Thus, it may be necessary  
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54 489 to adopt strategies according to the resources available at each facility, such as providing the  
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57 490 intervention initially to patients within reach and eventually to all individuals.  
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9 492 **4.4 Limitations**

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12 493 First, the intervention was provided in only two hospitals. In addition, only three staff members with  
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15 494 long clinical experience participated in the interviews to evaluate the intervention. Because this study  
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18 495 was not conducted across different regions, differently sized psychiatric hospitals, or in staff with  
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21 496 varied experience, the generalizability of the results may be limited. Second, we only examined the  
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24 497 opinions of patients who had consented to participation in the RCT for cancer screening  
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27 498 encouragement. This may lead to an overestimation of acceptability from the patients' perspective due  
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30 499 to volunteer bias.[23] In addition, patients who did not participate in this study may have more severe  
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33 500 psychiatric symptoms than those who did participate, and the feasibility of administering interventions  
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36 501 to such patients remains unknown. Third, for the interviews with providers, only three of the six  
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39 502 providers involved in the intervention participated. Therefore, the responses obtained in the present  
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42 503 study may not be representative of the opinions of the providers at the two facilities. Fourth, regarding  
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45 504 patient acceptability, we did not evaluate all seven components that comprise the theoretical  
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48 505 framework.[14]

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54 507 **5. CONCLUSION**55  
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57 508 The most essential component of the CM intervention according to patients was the in-person  
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6 509 counseling with an explanation of colorectal cancer screening by psychiatric care providers. From the  
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9 510 psychiatric care providers' perspective, the CM approach to encourage participation in colorectal  
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12 511 cancer screening was considered acceptable and appropriate. Although offering the intervention to all  
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15 512 patients eligible for cancer screening simultaneously may be difficult, the results indicated that the  
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18 513 intervention is easy to understand and administer. Further research, including the development of  
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21 514 educational methods for providers, is needed to implement this CM intervention in various psychiatric  
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24 515 clinical settings.  
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27 516

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9 528 **Contributors**

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15 530 MF1, TS, MK, RS, TM1, YY2, MF2, HT, NN, TM2, SH2, KH, HO, YU, NY, and MI participated in

16  
17  
18 531 the design of the study. MK, RS, TM1, YY2, and SH1 conducted the investigation. SH2 played a

19  
20  
21 532 primary role in designing the statistical analysis. YY1, MF1, and TE conducted the qualitative analysis.

22  
23  
24 533 TM2 played a primary role in designing the data management approach. YY1 and MF1 drafted the

25  
26  
27 534 manuscript. All authors revised the manuscript and approved the final version.

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51 560 authors have nothing to disclose.

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57 562 **Patient consent for publication**  
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12 565 **Ethics approval**  
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15 566 This study was approved by the institutional ethics committee at the Okayama University Graduate  
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33 572 **Data sharing statement**  
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36 573 The datasets in this study are not publicly available because of the terms of consent to which the  
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39 574 participants agreed but may be available from the corresponding author on reasonable request.  
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45 576 **6. REFERENCES**  
46  
47

48 577 1. Crump C, Winkleby MA, Sundquist K, et al. Comorbidities and mortality in persons with  
49  
50

51 578 schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170(3):324–33.  
52  
53

54 579 <https://doi.org/10.1176/appi.ajp.2012.12050599>.  
55  
56

57 580 2. Olfson M, Gerhard T, Huang C, et al. Premature mortality among adults with schizophrenia in  
58  
59  
60

- 1  
2  
3  
4  
5  
6 581 the United States. *JAMA Psychiatry* 2015;72(12):1172–81.  
7  
8  
9 582 <https://doi.org/10.1001/jamapsychiatry.2015.1737>.  
10  
11  
12 583 3. Pettersson D, Gissler M, Hällgren J, et al. The overall and sex- and age-group specific incidence  
13  
14  
15 584 rates of cancer in people with schizophrenia: a population-based cohort study. *Epidemiol*  
16  
17  
18 585 *Psychiatr Sci* 2020;29:e132. <https://doi.org/10.1017/S204579602000044X>.  
19  
20  
21 586 4. Zhuo C, Tao R, Jiang R, et al. Cancer mortality in patients with schizophrenia: systematic review  
22  
23  
24 587 and meta-analysis. *Br J Psychiatry* 2017;211(1):7–13.  
25  
26  
27 588 <https://doi.org/10.1192/bjp.bp.116.195776>.  
28  
29  
30 589 5. Hwong AR, Mangurian C. Improving breast cancer screening and care for women with severe  
31  
32  
33 590 mental illness. *J Clin Oncol* 2017;35(36):3996–8. <https://doi.org/10.1200/JCO.2017.76.0462>.  
34  
35  
36 591 6. Solmi M, Firth J, Miola A, et al. Disparities in cancer screening in people with mental illness  
37  
38  
39 592 across the world versus the general population: prevalence and comparative meta-analysis  
40  
41  
42 593 including 4 717 839 people. *Lancet Psychiatry* 2020;7(1):52–63. <https://doi.org/10.1016/S2215->  
43  
44  
45 594 0366(19)30414-6.  
46  
47  
48 595 7. Fujiwara M, Inagaki M, Nakaya N, et al. Cancer screening participation in schizophrenic  
49  
50  
51 596 outpatients and the influence of their functional disability on the screening rate: A cross-sectional  
52  
53  
54 597 study in Japan. *Psychiatry Clin Neurosci* 2017;71(12):813–25.  
55  
56  
57 598 <https://doi.org/10.1111/pcn.12554>.  
58  
59  
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2  
3  
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5  
6 599 8. Shin DW, Chang D, Jung JH, et al. Disparities in the participation rate of colorectal cancer  
7  
8  
9 600 screening by fecal occult blood test among people with disabilities: a national database study in  
10  
11  
12 601 South Korea. *Cancer Res Treat* 2020;52(1):60–73. <https://doi.org/10.4143/crt.2018.660>.  
13  
14  
15 602 9. Fujiwara M, Higuchi Y, Nakaya N, et al. Trends in cancer screening rates among individuals  
16  
17  
18 603 with serious psychological distress: an analysis of data from 2007 to 2016 Japanese national  
19  
20  
21 604 surveys, *J Psychosoc Oncol Res Pract* 2020;2(3):e025.  
22  
23  
24 605 <https://doi.org/10.1097/OR9.000000000000025>  
25  
26  
27 606 10. Fujiwara M, Inagaki M, Shimazu T, et al. A randomised controlled trial of a case management  
28  
29  
30 607 approach to encourage participation in colorectal cancer screening for people with schizophrenia  
31  
32  
33 608 in psychiatric outpatient clinics: study protocol for the J-SUPPORT 1901 (ACCESS) study. *BMJ*  
34  
35  
36 609 *Open* 2019;9(11):e032955. <https://doi.org/10.1136/bmjopen-2019-032955>.  
37  
38  
39 610 11. Fujiwara M, Yamada Y, Shimazu T, et al. Encouraging participation in colorectal cancer  
40  
41  
42 611 screening for people with schizophrenia: a randomized controlled trial. *Acta Psychiatr Scand*  
43  
44  
45 612 2021;144(4):318–28. <https://doi.org/10.1111/acps.13348>.  
46  
47  
48 613 12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual  
49  
50  
51 614 distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*  
52  
53  
54 615 2011;38(2):65–76. <https://doi.org/10.1007/s10488-010-0319-7>.  
55  
56  
57 616 13. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-  
58  
59  
60

- 1  
2  
3  
4  
5  
6 617 5. Washington, DC: American Psychiatric Association Publishing, 2013.  
7  
8  
9 618 14. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of  
10  
11  
12 619 reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17(1):88.  
13  
14  
15 620 <https://doi.org/10.1186/s12913-017-2031-8>.  
16  
17  
18 621 15. Cabinet Office, Government of Japan, Public Opinion Survey on Cancer Control (in Japanese).  
19  
20  
21 622 <https://survey.gov-online.go.jp/h28/h28-gantaisaku/2-2.html> [Accessed 19 Oct 2021].  
22  
23  
24 623 16. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the health belief model.  
25  
26  
27 624 *Health Education Quarterly* 1988;15(2):175–83. <https://doi.org/10.1177/109019818801500203>  
28  
29  
30 625 17. Proctor EK, Landsverk J, Aarons G, et al. Implementation research in mental health services: an  
31  
32  
33 626 emerging science with conceptual, methodological, and training challenges. *Adm Policy Ment*  
34  
35  
36 627 *Health* 2009;36(1):24–34. <https://doi.org/10.1007/s10488-008-0197-4>.  
37  
38  
39 628 18. Irwin KE, Henderson DC, Knight HP, et al. Cancer care for individuals with schizophrenia.  
40  
41  
42 629 *Cancer* 2014;120(3):323–34. <https://doi.org/10.1002/cncr.28431>.  
43  
44  
45 630 19. Weinstein LC, Stefancic A, Cunningham AT, et al. Cancer screening, prevention, and treatment  
46  
47  
48 631 in people with mental illness. *CA Cancer J Clin* 2016;66(2):134–51.  
49  
50  
51 632 <https://doi.org/10.3322/caac.21334>.  
52  
53  
54 633 20. Clifton A, Burgess C, Clement S, et al. Influences on uptake of cancer screening in mental health  
55  
56  
57 634 service users: a qualitative study. *BMC Health Serv Res* 2016;16:257. <https://doi.org/10.1186/s12913-016-1257-4>.  
58  
59  
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- 1  
2  
3  
4  
5  
6 635 [//doi.org/10.1186/s12913-016-1505-4](https://doi.org/10.1186/s12913-016-1505-4).
- 7  
8  
9 636 21. Friedman LC, Puryear LJ, Moore A, et al. Breast and colorectal cancer screening among low-  
10  
11  
12 637 income women with psychiatric disorders. *Psychooncology* 2005;14(9):786–91.  
13  
14  
15 638 <https://doi.org/10.1002/pon.906>.
- 16  
17  
18 639 22. Wells KJ, Battaglia TA, Dudley DJ, et al. Patient navigation: state of the art or is it science?  
19  
20  
21 640 *Cancer* 2008;113(8):1999–2010. <https://doi.org/10.1002/cncr.23815>.
- 22  
23  
24 641 23. Tarquinio C, Kivits J, Minary L, et al. Evaluating complex interventions: perspectives and issues  
25  
26  
27 642 for health behaviour change interventions. *Psychol Health* 2015;30(1):35–51.  
28  
29  
30 643 <https://doi.org/10.1080/08870446.2014.953530>.
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**Supplementary Table 1. Reasons for participation in cancer screening among the TAU group participants\***

		Patients in the TAU group who received cancer screening (N = 10)	
Categories	Patients' responses	N	%
Cue to action	Because it was encouraged in this study.	2	20.0
	Because it was encouraged by the primary psychiatrist.	0	0
	Because it was encouraged by my family physician.	2	20.0
	Because it was encouraged by my family.	0	0
	Because I received an invitation from the municipality.	0	0
	Because I had an upset stomach.	0	0
Perceived susceptibility	Because I was afraid of cancer.	0	0
	Because I had a family member with cancer.	1	10.0
	Because I had a friend with cancer.	0	0
	Because I had other physical illnesses.	0	0
Perceived benefit	Because I want to prevent cancer/detect cancer early.	2	20.0
Self-efficacy	Because I thought I could receive it.	0	0
Perceived barriers	Because it was not expensive.	1	10.0
	Because I found a clinic that was easy to visit.	0	0
Other	Because I receive cancer screening every year or sometimes.	6	60.0

\*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

Reasons for participation in cancer screening were classified by researchers into the following categories according to the Health Belief Model: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action, and self-efficacy.

Abbreviations: CM, case management; TAU, treatment as usual.

**Supplementary Table 2. Reasons for non-participation in cancer screening among the TAU group participants\***

Categories	Patients' responses	Patients in the TAU group who did not receive cancer screening (N = 65)	
		N	%
Perceived barriers	Because it was bothersome.	17	26.2
	Because I did not feel the necessity to receive it every year.	7	10.8
	Because there was no time.	9	13.8
	Because it was a financial burden.	2	3.1
	Because I had anxiety about having tests and being diagnosed with cancer.	1	1.5
	Because of obstacles to transport.	2	3.1
Perceived severity	Because I will visit a hospital when necessary.	11	16.9
Perceived susceptibility	Because I still have a long way to go before I get cancer.	2	3.1
Lack of knowledge	Because of the lack of knowledge about cancer screening.	5	7.7
Self-efficacy	Because I didn't feel like I could receive it.	2	3.1
Other	No particular reason.	4	6.2
<b>Content of free description**</b>			
Perceived barriers	Because of failure to receive cancer screening.	1	1.5
	Because of psychiatric symptoms.	3	4.6
Perceived severity	Because of the belief that cancer does not need to be detected/treated early.	3	4.6
Cue to action	Because I was not encouraged by my doctor to receive cancer screening.	2	3.1
	Because I recently had a colonoscopy.	2	3.1
Other	Because I was suspicious of this research.	0	0
	Because I failed to collect a stool specimen.	3	4.6

\*Multiple answers allowed. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

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6 \*\*For responses that did not fit predetermined options, the researchers coded the content of free  
7 descriptions and tabulated the number of responses.

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9 Reasons for non-participation in cancer screening were classified by researchers into the following  
10 categories according to the Health Belief Model: perceived susceptibility, perceived severity,  
11 perceived benefits, perceived barriers, cue to action, and self-efficacy.

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13 Abbreviations: CM, case management; TAU, treatment as usual.  
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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	<p>p.1</p>
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	<p>p.4, 5</p>

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	<p>p. 7, 8</p>
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	<p>p. 8</p>

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	<p>p. 8, 9</p>
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	<p>p. 14</p>
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	<p>p. 9-11</p>
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	<p>p. 9</p>
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	<p>p.8</p>
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	<p>p. 14, 15</p>

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	p.13, 14
6 7 8	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	p. 15, 16
9 10 11 12	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	p. 14, 15
13 14 15 16	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	p. 14, 15
17 18 19 20	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	p. 13-15

### Results/findings

23 24 25 26	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	p. 15-33
27 28 29	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	p. 19-28

### Discussion

32 33 34 35 36 37	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	p. 28-31
38 39	<b>Limitations</b> - Trustworthiness and limitations of findings	p. 31, 32

### Other

42 43 44	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	p. 34, 35
45 46	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	p. 34

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.



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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

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