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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

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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.

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

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

perceived by psychiatric care providers.

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

2. METHODS

2.1 Study design and participants

This study was a secondary analysis of a mixed-method RCT that evaluated the efficacy of the case management approach to encourage participation in cancer screening for people with schizophrenia. In this RCT, we interviewed study participants and psychiatric care providers who administered the intervention. All participants provided written informed consent prior to enrolment. This study is registered in the UMIN Clinical Trials Registry (UMIN000036017). The protocol of the trial, details of the intervention, and main trial findings were reported elsewhere.[10, 11] Therefore, the method of the trial is described briefly.

We recruited patients from two psychiatric outpatient clinics in Okayama City in Japan: the Okayama Psychiatric Medical Center (252 beds and approximately 250 outpatient visits per day) and

Zikei Hospital (570 beds and approximately 160 outpatient visits per day). Eligible participants were aged ≥ 40 years in the 2019 fiscal year; had visited the recruitment sites as their primary psychiatric outpatient service; and were outpatients diagnosed by their current primary psychiatrist with schizophrenia or schizoaffective disorder, according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.[13] Key exclusion criteria were patients with a history of colorectal cancer; those living in an institution where residents were supported in receiving cancer screening; and patients judged to be at risk of symptom worsening by participating in the study.

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

2.2 Cancer screening program provided by the municipality

In Japan, screenings for colorectal, gastric, lung, breast, and cervical cancer provided by local governments are available with a low co-payment. In this study, we recommended colorectal cancer screening using the FOBT for individuals aged 40 years and older. The cancer screening program of Okayama City does not mail the FOBT kit in advance. Instead, individuals select a clinic offering cancer screening and make an appointment to visit the clinic to receive the kit. Although individuals with a low household income can receive free screening, eligible individuals must apply for a coupon

in advance at the municipal office.

The Okayama municipal government distributes a leaflet and detailed brochure encouraging participation in the above cancer screening program to all households in the city once a year.

2.3 Case management intervention to encourage participation in cancer screening

A case manager (nurse or psychiatric social worker) provided three counseling sessions to the study participants allocated to the CM plus TAU group.

The first session, which was conducted in person, comprised the following components: a) education on the importance and content of colorectal cancer screening, using a pamphlet, b) assistance in making decisions and an appointment for colorectal cancer screening, and c) assistance in obtaining a coupon for free screening, if necessary. Other cancer screening was also briefly mentioned using the pamphlet. Education on cancer screening using the pamphlet did not take the approach whereby the seriousness or severity of cancer was emphasized.

After the first in-person session, a case manager provided at least two follow-up in-person or telephone counseling sessions to remind or support the patient's participation in cancer screening. The follow-up session could be skipped if the subject was judged to be able to receive cancer screening without the follow-up sessions.

This intervention was standardized in the form of a manual. Psychiatric nurses or social

workers who had already worked at the study sites administered the intervention as case managers, according to the procedures described in the manual.

2.4 Follow-up interview conducted after the end of the intervention period

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

2.4.1 Interviews with patients

In a structured interview, the case manager asked the CM plus TAU group participants about "patients' acceptability of the intervention," "helpful components of the intervention," and "reasons for participation or non-participation in cancer screening."

For *patients' acceptability of the intervention*, patients were asked about "affective attitude," which is one of the components of the theoretical framework of acceptability.[14] This theoretical framework was developed according to the overview of systematic reviews focusing on patients' acceptability of healthcare interventions.[14] Patients were asked, "how do you feel about this recommendation for cancer screening?"

For *helpful components of the intervention*, patients were asked to describe the components of the intervention that they perceived as helpful. The interviewer categorized patients' open-ended

responses into the following components of the intervention: assignment of a case manager; explanation of colorectal cancer screening; explanation of the coupon for free screening; planning a schedule for the cancer screening; and follow-up contact at a later date. Patients were asked, "what was helpful in this intervention?"

For *reasons for participation or non-participation in cancer screening*, patients were asked to describe their reasons for participation or non-participation with an open-ended question. The interviewers categorized patients' responses into predetermined options, which were based on a Japanese public opinion survey on cancer control,[15] and were classified into the following categories based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.[16] Patients were asked, "what were your reasons for participating or not participating in colorectal cancer screening?"

2.4.2 Interviews with providers

A group interview was conducted with providers to assess the implementation outcomes of the intervention. Proctor et al. proposed the Implementation Outcomes Framework,[17] which conceptualizes the variables of interest in implementation evaluation. Among the implementation outcomes included in this framework, we investigated "acceptability," "appropriateness," and "feasibility," which were all measurable factors in this study.

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

validity of the results. For "patients' acceptability of the intervention," the open-ended responses were coded following a discussion between two researchers (Y.Y., a psychiatrist with 6 years of clinical experience, and T.E., a nurse with more than 10 years of clinical experience). For "helpful components of the intervention," "reasons for participation in cancer screening," and "reasons for non-participation in cancer screening," responses obtained from the interviews were categorized into predetermined options by the interviewers. Answers that did not fit into the predetermined options were coded by the same researchers. Responses to "patients' acceptability of the intervention" and "helpful components of the intervention" were stratified according to whether patients had received cancer screening.

For the data obtained from the interviews with providers, the researcher extracted and summarized the opinions obtained from the verbatim transcripts and asked the interviewees to revise and confirm the summarized descriptions.

2.6 Patient and public involvement statement

Patients were not directly involved in the development of the research questions and interventions or in the design of the planned study. We obtained patients' feedback regarding the intervention in this study. The results of the study will be published on our facilities' and funder's website.

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)
Age, years			
Median (range)	52 (39, 74)	54 (39, 80)	53 (39, 80)
Sex			
Women	37 (47.4%)	35 (46.7%)	72 (47.1%)
Educational level*			
≤ 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%)
Marital status*			
Married	9 (11.5%)	8 (10.7%)	17 (11.1%)
Living alone*			
Yes	39 (50.0%)	36 (48.0%)	75 (49.0%)
Current outpatient for physical illness*			
Yes	38 (48.7%)	35 (46.7%)	73 (47.7%)
History of receiving colorectal cancer screening*			
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%)
mGAF score			
Mean (SD)	49.6 (15.7)	50.9 (14.8)	50.2 (15.2)
Range	15, 85	25, 85	15, 85
Participation in colorectal cancer screening			
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.

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

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

"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*

		Patients in CM plus TAU group who received cancer screening (N = 39)	
Categories	Patients' responses	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
	Because I had other physical illnesses.	3	7.7
Perceived benefit	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

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

"I didn't receive it because I have good bowel movements." ID 67

"I didn't receive it because I had already had the screening before, and I thought I didn't need to take it again." ID 160

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

"I misunderstood the period during which the screening was conducted." ID 75

"I was going to see the doctor, but I forgot my coupon for free screening." ID 4

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

		Patients in the CM plus TAU group who did not receive cancer screening (N = 39)	
Categories	Patients' responses	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
Content of free description			
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
• It is an acceptable intervention for psychiatric clinics to provide encouragement.
Appropriateness
• 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.
Feasibility
• 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.

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

"During the follow-up sessions, few patients changed their intentions of receiving/not-receiving cancer screening or required additional support. Follow-up sessions may not be necessary for all patients." Psychiatric social worker, 25 years of clinical experience

In terms of "feasibility," the following comments were made:

"This intervention will take some getting used to but will not require time-consuming training sessions. Once explained, it is possible to carry out the intervention in accordance with the procedures." Psychiatric social worker, 25 years of clinical experience

"This intervention could be administered quickly for patients who have a history of undergoing cancer screening. As the number of those who have undergone cancer screening increases, the burden on case managers will be reduced." Psychiatric social worker, 25 years of clinical experience

"It is difficult to encourage all eligible patients for colorectal cancer screening at once in terms of human resources. The impact of the COVID-19 epidemic made it even more difficult." Nurse, 20 years of clinical experience

4. DISCUSSION

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

4.1 ***Patients' acceptability and helpful components of the intervention***

From the patients' perspective, evaluations of the intervention were mostly positive, which suggested that there is patient demand for this intervention. In addition, few patients, including those who did not receive colorectal cancer screening, reported any discomfort or anxiety about receiving the intervention. This suggests that this intervention method is acceptable to most patients.

Regarding the components of the intervention that were considered helpful, most patients reported that the explanation of the colorectal cancer screening process was helpful. Patients with schizophrenia have barriers to accessing and understanding information about cancer screening.[18,

19] Moreover, many patients may not have been aware of the information distributed by the municipality (i.e., the leaflet and brochure) or understood the procedure to receive colorectal cancer screening. The present findings suggest that providing direct and individualized explanations is effective in addressing these barriers.

4.2 Reasons for participation or non-participation in cancer screening

The largest proportion of patients stated that being encouraged in this study was the reason for receiving cancer screening. This suggests that the CM intervention acted as an effective cue to undergo cancer screening. This is consistent with a previous finding that physicians' recommendation of screening is the strongest predictor of patients receiving cancer screening in those with psychiatric disorders.[20] Furthermore, as other reasons for receiving screening, numerous patients highlighted the desire for prevention/early detection of cancer and the low cost of cancer screening. This suggests that the intervention was able to address the perceived benefits and barriers of patients with schizophrenia. Few patients responded that fear of cancer was the reason for undergoing colorectal cancer screening. This may be because the intervention did not emphasize the seriousness or severity of cancer. In addition, a significant number of patients answered that they underwent cancer screening because they had done so every year. Therefore, a simple intervention may be sufficient for such patients. It is essential to encourage patients to undergo consistent colorectal cancer screening every

year.

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

4.3 Acceptability, appropriateness, and feasibility of the intervention from the providers' perspective

The providers who provided the intervention evaluated it as an "acceptable" approach to encourage participation in cancer screening at the psychiatric outpatient clinic. Supporting the physical health of patients with mental illness was considered an important role of psychiatric outpatient clinics, and thus awareness of this issue should be raised within clinics when implementing the intervention.

It was also perceived as "appropriate" to provide patients with tailored navigation on cancer screening procedures. The CM intervention was considered appropriate because many patients

reported that they were able to complete the procedure themselves after receiving the individualized intervention. Patient navigation has been gaining interest as an approach to reducing disparities in cancer screening and diagnosis.[21] This was an essential component of the CM intervention.

In this study, providers perceived that it was easy to understand the content of and administer the intervention. This suggests that it is likely to be "feasible" for implementing in routine clinical practice. However, there are also challenges to the implementation of the intervention in a clinical setting in terms of resources. In particular, providers considered it would be difficult to deliver the intervention to all eligible patients simultaneously. Thus, it may be necessary to adopt strategies according to the resources available at each facility, such as providing the intervention initially to patients within reach and eventually to all individuals.

4.4 Limitations

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

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. Masaki Fujiwara reports grants from the Japanese MHLW, received during the conduct of the study, and personal fees from Meiji outside of the submitted work. Taichi Shimazu reports grants from the MHLW, received during the conduct of the study. Masafumi Kodama reports grants from the MHLW, received during the conduct of the study. Ryuhei So reports personal fees from Kagakuhyoronsha, Medical Review, Otsuka, Igaku Shoin, and CureApp outside of the submitted work. Yusaku Yoshimura reports personal fees from Otsuka, Janssen, and Meiji outside of the submitted work. Tempei Miyaji reports grants from the MHLW, received during the conduct of the study. Yosuke Uchitomi reports grants from the MHLW and grants and non-financial support from the Japan Health Research Promotion Bureau and the National Cancer Center Japan, received during the conduct of the study. Norihito Yamada reports grants from the MHLW, received during the conduct of the study; grants and personal fees from Daiichi Sankyo, Eisai, and Takeda; and personal fees from Otsuka, MSD, UCB, and Sumitomo Dainippon outside of the submitted work. Masatoshi Inagaki reports grants from the MHLW, received during the conduct of the study; personal fees from Technomics, Fuji Keizai, Novartis, Pfizer, MSD, Yoshitomiyakuhin, Meiji, Eisai, Otsuka, Sumitomo Dainippon, Mochida, Janssen, Takeda, and Eli Lilly; and grants from Otsuka, Eisai, Daiichi Sankyo, Pfizer, Astellas, MSD, Takeda, Fujifilm, Shionogi, and Mochida outside of the submitted work. All other

authors have nothing to disclose.

Patient consent for publication

Not required.

Ethics approval

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

Data sharing statement

The datasets in this study are not publicly available because of the terms of consent to which the participants agreed but may be available from the corresponding author on reasonable request.

6. REFERENCES

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

schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170(3):324–33. https://doi.org/10.1176/appi.ajp.2012.12050599.

2. Olfson M, Gerhard T, Huang C, et al. Premature mortality among adults with schizophrenia in the United States. *JAMA Psychiatry* 2015;72(12):1172–81. https://doi.org/10.1001/jamapsychiatry.2015.1737.

3. Pettersson D, Gissler M, Hällgren J, et al. The overall and sex- and age-group specific incidence rates of cancer in people with schizophrenia: a population-based cohort study. *Epidemiol Psychiatr Sci* 2020;29:e132. https://doi.org/10.1017/S204579602000044X.

4. Zhuo C, Tao R, Jiang R, et al. Cancer mortality in patients with schizophrenia: systematic review and meta-analysis. *Br J Psychiatry* 2017;211(1):7–13. https://doi.org/10.1192/bjp.bp.116.195776.

5. Hwong AR, Mangurian C. Improving breast cancer screening and care for women with severe mental illness. *J Clin Oncol* 2017;35(36):3996–8. https://doi.org/10.1200/JCO.2017.76.0462.

6. Solmi M, Firth J, Miola A, et al. Disparities in cancer screening in people with mental illness across the world versus the general population: prevalence and comparative meta-analysis including 4 717 839 people. *Lancet Psychiatry* 2020;7(1):52–63. https://doi.org/10.1016/S2215-0366(19)30414-6.

7. Fujiwara M, Inagaki M, Nakaya N, et al. Cancer screening participation in schizophrenic

outpatients and the influence of their functional disability on the screening rate: A cross-sectional study in Japan. *Psychiatry Clin Neurosci* 2017;71(12):813–25. https://doi.org/10.1111/pcn.12554.

8. Shin DW, Chang D, Jung JH, et al. Disparities in the participation rate of colorectal cancer screening by fecal occult blood test among people with disabilities: a national database study in South Korea. *Cancer Res Treat* 2020;52(1):60–73. https://doi.org/10.4143/crt.2018.660.
9. Fujiwara M, Higuchi Y, Nakaya N, et al. Trends in cancer screening rates among individuals with serious psychological distress: an analysis of data from 2007 to 2016 Japanese national surveys, *J Psychosoc Oncol Res Pract* 2020;2(3):e025. https://doi.org/10.1097/OR9.0000000000000025
10. Fujiwara M, Inagaki M, Shimazu T, et al. A randomised controlled trial of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia in psychiatric outpatient clinics: study protocol for the J-SUPPORT 1901 (ACCESS) study. *BMJ Open* 2019;9(11):e032955. https://doi.org/10.1136/bmjopen-2019-032955.
11. Fujiwara M, Yamada Y, Shimazu T, et al. Encouraging participation in colorectal cancer screening for people with schizophrenia: a randomized controlled trial. *Acta Psychiatr Scand* 2021;144(4):318–28. https://doi.org/10.1111/acps.13348.
12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual

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.

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	
Title - 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.1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	p.4, 5
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	p. 7, 8
Purpose or research question - Purpose of the study and specific objectives or questions	p. 8
Methods	
Qualitative approach and research paradigm - 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. 9
Researcher characteristics and reflexivity - 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. 15
Context - Setting/site and salient contextual factors; rationale**	p. 9-11
Sampling strategy - 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. 9, 10
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	p. 9
Data collection methods - 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. 15

Data collection instruments and technologies - 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
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	p. 16, 17
Data processing - 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
Data analysis - 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
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	p. 14, 15

Results/findings

Synthesis and interpretation - 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
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic finSdings	p. 19-28

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - 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
Limitations - Trustworthiness and limitations of findings	p. 32, 33

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	p. 35, 36
Funding - 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.

**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
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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 qualitative secondary analysis of a mixed-method randomized clinical trial

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Primary Subject Heading:	Mental health

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

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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 qualitative secondary analysis of a mixed-method randomized clinical trial

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Word count: **3755 words**

ABSTRACT (300 words)

Objectives

We examined the efficacy of case management (CM) interventions to encourage participation in colorectal cancer screening for schizophrenia patients. This study aimed to clarify patients' acceptability of the intervention and helpful components of the intervention. 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. The intervention comprised education and patient navigation for colorectal cancer screening. Interviews were conducted with patients 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 addition, three out of six providers were included.

Data collection and analysis

Using a structured interview, the case manager asked participants about patient acceptability and helpful components of the intervention. Content analysis was conducted for the responses obtained, and the number of responses was tabulated by two researchers. For the interviews with the providers, opinions obtained from verbatim transcripts were extracted and summarized.

Results

Forty-three of the 56 patients perceived that the intervention was acceptable. For the intervention component, in-person counseling with an explanation of the screening process by psychiatric care providers was most frequently reported as helpful by patients (48 of the 68 respondents). 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 study showed that the CM intervention was perceived as acceptable by patients and acceptable and appropriate by psychiatric care providers.

Keywords

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

Trial registration

UMIN000036017

Strengths and limitations of the study

- This study was designed to incorporate a pre-planned qualitative study into a randomized controlled trial.
- Information related to the implementation of the intervention, as assessed by patients and psychiatric care providers, was organized according to theoretical frameworks.
- 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.
- We did not investigate psychiatric hospitals of all sizes/regions, which limits the generalizability of the present results.

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] In psychiatric medical settings, CM, which includes the planning and coordinating of necessary services for community life, is commonly implemented. CM may also include advice on maintaining physical health and referral to appropriate specialists. The present intervention provided education and navigation regarding cancer screening as a part of CM in daily clinical practice.

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 perceived by psychiatric care providers.

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

2. METHODS

2.1 Study design and participants

This study was a secondary analysis of a mixed-method RCT that evaluated the efficacy of the CM approach to encourage participation in cancer screening for people with schizophrenia. In this RCT, we interviewed study participants and psychiatric care providers who administered the intervention. All participants provided written informed consent prior to enrollment. This study is registered in the UMIN Clinical Trials Registry (UMIN000036017). The protocol of the trial, details of the intervention,

and main trial findings were reported elsewhere.[10, 11] Therefore, the method of the trial is described briefly.

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

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

2.2 Cancer screening program provided by the municipality

In Japan, the Ministry of Health, Labour and Welfare (MHLW) recommends population-based cancer screening for colorectal, gastric, lung, breast, and cervical cancer. These screenings are provided by

local governments with a low co-payment. In this study, we recommended colorectal cancer screening using the FOBT for individuals aged 40 years and older. The cancer screening program of Okayama City does not mail the FOBT kit in advance. Instead, individuals select a clinic offering cancer screening and make an appointment to visit the clinic to receive the kit. Although individuals with a low household income can receive free screening, eligible individuals must apply for a coupon in advance at the municipal office.

The Okayama municipal government distributes a leaflet and detailed brochure encouraging participation in the above cancer screening program to all households in the city once a year.

2.3 Case management intervention to encourage participation in cancer screening

A case manager (nurse or psychiatric social worker) provided three counseling sessions to the study participants allocated to the CM plus TAU group. The CM intervention aimed to educate and navigate patients around colorectal cancer screening.

The first session, which was conducted in person, comprised the following components: a) education on the importance and content of colorectal cancer screening, using a pamphlet, b) assistance in making decisions and an appointment for colorectal cancer screening, and c) assistance in obtaining a coupon for free screening, if necessary. Other cancer screening was also briefly mentioned using the pamphlet. Education on cancer screening using the pamphlet did not take the

approach whereby the seriousness or severity of cancer was emphasized.

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

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

2.4 Follow-up interview conducted after the end of the intervention period

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

2.4.1 Interviews with patients

In a structured interview, the case manager asked the CM plus TAU group participants about "patients' acceptability of the intervention," "helpful components of the intervention," and "reasons for participation or non-participation in cancer screening."

For *patients' acceptability of the intervention*, patients were asked about "affective attitude," which is one of the components of the theoretical framework of acceptability.[14] This theoretical framework was developed according to the overview of systematic reviews focusing on patients' acceptability of healthcare interventions.[14] We selected the affective attitude that was considered most helpful in disseminating the intervention. Patients were asked, "how do you feel about this recommendation for cancer screening?"

For *helpful components of the intervention*, patients were asked to describe the components of the intervention that they perceived as helpful. The interviewer categorized patients' open-ended responses into the following components of the intervention: assignment of a case manager; explanation of colorectal cancer screening; explanation of the coupon for free screening; planning a schedule for the cancer screening; and follow-up contact at a later date. Patients were asked, "what was helpful in this intervention?"

For *reasons for participation or non-participation in cancer screening*, patients were asked to describe their reasons for participation or non-participation with an open-ended question. The interviewers categorized patients' responses into predetermined options, which were based on a

Japanese public opinion survey on cancer control,[15] and were classified into the following categories based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.[16] Patients were asked, "what were your reasons for participating or not participating in colorectal cancer screening?"

The interviewer summarized the content immediately after the responses were obtained, and the interviews with patients were not recorded.

2.4.2 Interviews with providers

A group interview was conducted with providers to assess the implementation outcomes of the intervention. Proctor et al. proposed the Implementation Outcomes Framework,[17] which conceptualizes the variables of interest in implementation evaluation. Among the implementation outcomes included in this framework, we investigated "acceptability," "appropriateness," and "feasibility," which were all measurable factors in this study.

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 validity of the results. For "patients' acceptability of the intervention," content analysis was performed on the patients' responses described by interviewers. The open-ended responses were coded following a discussion between two researchers (YY, a psychiatrist with 6 years of clinical experience, and TE, a nurse with more than 10 years of clinical experience), and the number of responses was tabulated according to the codes created. For "helpful components of the intervention," "reasons for

participation in cancer screening," and "reasons for non-participation in cancer screening," the open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers. Answers that did not fit into the predetermined options were coded by the same researchers, and the number of responses was tabulated according to the codes created. Responses to "patients' acceptability of the intervention" and "helpful components of the intervention" were stratified according to whether patients had received cancer screening.

For the data obtained from the interviews with providers, the researcher extracted and summarized the opinions obtained from the verbatim transcripts and asked the interviewees to revise and confirm the summarized descriptions.

2.6 Patient and public involvement statement

Patients were not directly involved in the development of the research questions and interventions or in the design of the planned study. We obtained patients' feedback regarding the intervention in this study. The results of the study will be published on our facilities' and funder's website.

3. RESULTS

3.1 Patient enrollment 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)
Age, years			
Median (range)	52 (39, 74)	54 (39, 80)	53 (39, 80)
Sex			
Women	37 (47.4%)	35 (46.7%)	72 (47.1%)
Educational level*			
≤ 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%)
Marital status*			
Married	9 (11.5%)	8 (10.7%)	17 (11.1%)
Living alone*			
Yes	39 (50.0%)	36 (48.0%)	75 (49.0%)
Current outpatient for physical illness*			
Yes	38 (48.7%)	35 (46.7%)	73 (47.7%)
History of receiving colorectal cancer screening*			
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%)
mGAF score			
Mean (SD)	49.6 (15.7)	50.9 (14.8)	50.2 (15.2)
Range	15, 85	25, 85	15, 85
Participation in colorectal cancer screening			
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%)

*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.

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

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. Content analysis was performed by the researchers, and the number of responses was tabulated according to the codes created.

†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 TAU 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

"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. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

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 TAU 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*

		Patients in CM plus TAU group who received cancer screening (N = 39)	
Categories	Patients' responses	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
	Because I had other physical illnesses.	3	7.7
Perceived benefit	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. 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 based on the Health Belief Model: perceived susceptibility; perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.

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

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

"I didn't receive it because I have good bowel movements." ID 67

"I didn't receive it because I had already had the screening before, and I thought I didn't need to take it again." ID 160

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

"I misunderstood the period during which the screening was conducted." ID 75

"I was going to see the doctor, but I forgot my coupon for free screening." ID 4

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
Content of free description**			
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. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

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

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.

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

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

- 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.

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

"During the follow-up sessions, few patients changed their intentions of receiving/not receiving cancer screening or required additional support. Follow-up sessions may not be necessary for all patients." Psychiatric social worker, 25 years of clinical experience

In terms of "feasibility," the following comments were made:

"This intervention will take some getting used to but will not require time-consuming training sessions. Once explained, it is possible to carry out the intervention in accordance with the procedures." Psychiatric social worker, 25 years of clinical experience

"This intervention could be administered quickly for patients who have a history of undergoing cancer screening. As the number of those who have undergone cancer screening increases, the burden on case managers will be reduced." Psychiatric social worker, 25 years of clinical experience

"It is difficult to encourage all eligible patients for colorectal cancer screening at once in terms of human resources. The impact of the COVID-19 epidemic made it even more difficult." Nurse, 20 years of clinical experience

4. DISCUSSION

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

4.1 *Patients' acceptability and helpful components of the intervention*

From the patients' perspective, evaluations of the intervention were mostly positive, which suggested that there is patient demand for this intervention. In addition, few patients, including those who did

not receive colorectal cancer screening, reported any discomfort or anxiety about receiving the intervention. This suggests that this intervention method is acceptable to most patients.

Regarding the components of the intervention that were considered helpful, most patients reported that the explanation of the colorectal cancer screening process was helpful. Patients with schizophrenia have barriers to accessing and understanding information about cancer screening and those related to practical issues. [18-20] Moreover, many patients may not have been aware of the information distributed by the municipality (i.e., the leaflet and brochure) or understood the procedure to receive colorectal cancer screening. The present findings suggest that providing direct and individualized explanations is effective in addressing these barriers.

4.2 Reasons for participation or non-participation in cancer screening

The largest proportion of patients stated that being encouraged in this study was the reason for receiving cancer screening. This suggests that the CM intervention acted as an effective cue to undergo cancer screening. This is consistent with a previous finding that physicians' recommendation of screening is the strongest predictor of patients receiving cancer screening in those with psychiatric disorders.[21] Furthermore, as other reasons for receiving screening, numerous patients highlighted the desire for prevention/early detection of cancer and the low cost of cancer screening. This suggests that the intervention was able to address the perceived benefits and barriers of patients with

schizophrenia. Few patients responded that fear of cancer was the reason for undergoing colorectal cancer screening. This may be because the intervention did not emphasize the seriousness or severity of cancer. In addition, a significant number of patients answered that they underwent cancer screening because they had done so every year. Therefore, a simple intervention may be sufficient for such patients. It is essential to encourage patients to undergo consistent colorectal cancer screening every year.

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

4.3 Acceptability, appropriateness, and feasibility of the intervention from the providers' perspective

The providers who provided the intervention evaluated it as an "acceptable" approach to encourage

participation in cancer screening at the psychiatric outpatient clinic. Supporting the physical health of patients with mental illness was considered an important role of psychiatric outpatient clinics, and thus awareness of this issue should be raised within clinics when implementing the intervention.

It was also perceived as "appropriate" to provide patients with tailored navigation on cancer screening procedures. The CM intervention was considered appropriate because many patients reported that they were able to complete the procedure themselves after receiving the individualized intervention. Patient navigation has been gaining interest as an approach to reducing disparities in cancer screening and diagnosis.[22] This was an essential component of the CM intervention.

In this study, providers perceived that it was easy to understand the content of and administer the intervention. This suggests that it is likely to be "feasible" for implementing in routine clinical practice. However, there are also challenges to the implementation of the intervention in a clinical setting in terms of resources. In particular, providers considered it would be difficult to deliver the intervention to all eligible patients simultaneously. There are currently insufficient outpatient staff to provide interventions to the large number of outpatients who visit each day. Thus, it may be necessary to adopt strategies according to the resources available at each facility, such as providing the intervention initially to patients within reach and eventually to all individuals.

4.4 Limitations

First, the intervention was provided in only two hospitals. In addition, only three staff members with

long clinical experience participated in the interviews to evaluate the intervention. Because this study was not conducted across different regions, differently sized psychiatric hospitals, or in staff with varied experience, the generalizability of the results may be limited. Second, we only examined the opinions of patients who had consented to participation in the RCT for cancer screening encouragement. This may lead to an overestimation of acceptability from the patients' perspective due to volunteer bias.[23] In addition, patients who did not participate in this study may have more severe psychiatric symptoms than those who did participate, and the feasibility of administering interventions to such patients remains unknown. Third, for the interviews with providers, only three of the six providers involved in the intervention participated. Therefore, the responses obtained in the present study may not be representative of the opinions of the providers at the two facilities. Fourth, regarding patient acceptability, we did not evaluate all seven components that comprise the theoretical framework.[14]

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, including the development of educational methods for providers, is needed to implement this CM intervention in various psychiatric clinical settings.

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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. Masaki Fujiwara reports grants from the Japanese MHLW, received during the conduct of the study, and personal fees from Meiji outside of the submitted work. Taichi Shimazu reports grants from the MHLW, received during the conduct of the study. Masafumi Kodama reports grants from the MHLW, received during the conduct of the study. Ryuhei So reports personal fees from Kagakuhyoronsha,

Medical Review, Otsuka, Igaku Shoin, and CureApp outside of the submitted work. Yusaku Yoshimura reports personal fees from Otsuka, Janssen, and Meiji outside of the submitted work. Tempei Miyaji reports grants from the MHLW, received during the conduct of the study. Yosuke Uchitomi reports grants from the MHLW and grants and non-financial support from the Japan Health Research Promotion Bureau and the National Cancer Center Japan, received during the conduct of the study. Norihito Yamada reports grants from the MHLW, received during the conduct of the study; grants and personal fees from Daiichi Sankyo, Eisai, and Takeda; and personal fees from Otsuka, MSD, UCB, and Sumitomo Dainippon outside of the submitted work. Masatoshi Inagaki reports grants from the MHLW, received during the conduct of the study; personal fees from Technomics, Fuji Keizai, Novartis, Pfizer, MSD, Yoshitomiyakuhin, Meiji, Eisai, Otsuka, Sumitomo Dainippon, Mochida, Janssen, Takeda, and Eli Lilly; and grants from Otsuka, Eisai, Daiichi Sankyo, Pfizer, Astellas, MSD, Takeda, Fujifilm, Shionogi, and Mochida outside of the submitted work. All other authors have nothing to disclose.

Patient consent for publication

Not required.

Ethics approval

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

Data sharing statement

The datasets in this study are not publicly available because of the terms of consent to which the participants agreed but may be available from the corresponding author on reasonable request.

6. REFERENCES

1. Crump C, Winkleby MA, Sundquist K, et al. Comorbidities and mortality in persons with schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170(3):324–33. https://doi.org/10.1176/appi.ajp.2012.12050599.
2. Olfson M, Gerhard T, Huang C, et al. Premature mortality among adults with schizophrenia in the United States. *JAMA Psychiatry* 2015;72(12):1172–81. https://doi.org/10.1001/jamapsychiatry.2015.1737.
3. Pettersson D, Gissler M, Hällgren J, et al. The overall and sex- and age-group specific incidence

584 rates of cancer in people with schizophrenia: a population-based cohort study. *Epidemiol*
585 *Psychiatr Sci* 2020;29:e132. https://doi.org/10.1017/S204579602000044X.
586 4. Zhuo C, Tao R, Jiang R, et al. Cancer mortality in patients with schizophrenia: systematic review
587 and meta-analysis. *Br J Psychiatry* 2017;211(1):7–13.
588 https://doi.org/10.1192/bjp.bp.116.195776.
589 5. Hwong AR, Mangurian C. Improving breast cancer screening and care for women with severe
590 mental illness. *J Clin Oncol* 2017;35(36):3996–8. https://doi.org/10.1200/JCO.2017.76.0462.
591 6. Solmi M, Firth J, Miola A, et al. Disparities in cancer screening in people with mental illness
592 across the world versus the general population: prevalence and comparative meta-analysis
593 including 4 717 839 people. *Lancet Psychiatry* 2020;7(1):52–63. https://doi.org/10.1016/S2215-
594 0366(19)30414-6.
595 7. Fujiwara M, Inagaki M, Nakaya N, et al. Cancer screening participation in schizophrenic
596 outpatients and the influence of their functional disability on the screening rate: A cross-sectional
597 study in Japan. *Psychiatry Clin Neurosci* 2017;71(12):813–25.
598 https://doi.org/10.1111/pcn.12554.
599 8. Shin DW, Chang D, Jung JH, et al. Disparities in the participation rate of colorectal cancer
600 screening by fecal occult blood test among people with disabilities: a national database study in
601 South Korea. *Cancer Res Treat* 2020;52(1):60–73. https://doi.org/10.4143/crt.2018.660.

9. Fujiwara M, Higuchi Y, Nakaya N, et al. Trends in cancer screening rates among individuals with serious psychological distress: an analysis of data from 2007 to 2016 Japanese national surveys, *J Psychosoc Oncol Res Pract* 2020;2(3):e025. https://doi.org/10.1097/OR9.0000000000000025

10. Fujiwara M, Inagaki M, Shimazu T, et al. A randomised controlled trial of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia in psychiatric outpatient clinics: study protocol for the J-SUPPORT 1901 (ACCESS) study. *BMJ Open* 2019;9(11):e032955. https://doi.org/10.1136/bmjopen-2019-032955.

11. Fujiwara M, Yamada Y, Shimazu T, et al. Encouraging participation in colorectal cancer screening for people with schizophrenia: a randomized controlled trial. *Acta Psychiatr Scand* 2021;144(4):318–28. https://doi.org/10.1111/acps.13348.

12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual 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. https://doi.org/10.3322/caac.21334.

20. Clifton A, Burgess C, Clement S, et al. Influences on uptake of cancer screening in mental health service users: a qualitative study. *BMC Health Serv Res* 2016;16:257. https://doi.org/10.1186/s12913-016-1505-4.

21. 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.

22. 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.

23. 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.

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*

		Patients in the TAU group who did not receive cancer screening (N = 65)	
Categories	Patients' responses	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
Content of free description**			
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
Other	Because I recently had a colonoscopy.	2	3.1
	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.

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

Reasons for non-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.

Standards for Reporting Qualitative Research (SRQR)*

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

	Page/line no(s).
Title and abstract	
Title - 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.1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	p.4, 5
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	p. 7, 8
Purpose or research question - Purpose of the study and specific objectives or questions	p. 8
Methods	
Qualitative approach and research paradigm - 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. 8, 9
Researcher characteristics and reflexivity - 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. 14
Context - Setting/site and salient contextual factors; rationale**	p. 9-11
Sampling strategy - 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. 9
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	p.8
Data collection methods - 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. 14, 15

Data collection instruments and technologies - 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
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	p. 15, 16
Data processing - 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
Data analysis - 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
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	p. 13-15

Results/findings

Synthesis and interpretation - 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
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic finSdings	p. 19-28

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - 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
Limitations - Trustworthiness and limitations of findings	p. 31, 32

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	p. 34, 35
Funding - 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.

**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
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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 qualitative secondary analysis of a mixed-method randomized clinical trial

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Primary Subject Heading:	Mental health

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

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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 qualitative secondary analysis of a mixed-method randomized clinical trial

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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. This study aimed to clarify patients' acceptability of the intervention and helpful components of the intervention. 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. The intervention comprised education and patient navigation for colorectal cancer screening. Interviews were conducted with patients 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 addition, three out of six providers were included.

Data collection and analysis

Using a structured interview, the case manager asked participants about patient acceptability and helpful components of the intervention. Content analysis was conducted for the responses obtained, and the number of responses was tabulated by two researchers. For the interviews with the providers, opinions obtained from verbatim transcripts were extracted and summarized.

Results

Forty-three of the 56 patients perceived that the intervention was acceptable. For the intervention component, in-person counseling with an explanation of the screening process by psychiatric care providers was most frequently reported as helpful by patients (48 of the 68 respondents). 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 study showed that the CM intervention was perceived as acceptable by patients and acceptable and appropriate by psychiatric care providers.

Keywords

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

Trial registration

UMIN000036017

Strengths and limitations of the study

- This study was designed to incorporate a pre-planned qualitative study into a randomized controlled trial.
- Information related to the implementation of the intervention, as assessed by patients and psychiatric care providers, was organized according to theoretical frameworks.
- 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.
- We did not investigate psychiatric hospitals of all sizes/regions, which limits the generalizability of the present results.

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] In psychiatric medical settings, CM, which includes the planning and coordinating of necessary services for community life, is commonly implemented. CM may also include advice on maintaining physical health and referral to appropriate specialists. The present intervention provided education and navigation regarding cancer screening as a part of CM in daily clinical practice.

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 perceived by psychiatric care providers.

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

2. METHODS

2.1 Study design and participants

This study was a secondary analysis of a mixed-method RCT that evaluated the efficacy of the CM approach to encourage participation in cancer screening for people with schizophrenia. In this RCT, we interviewed study participants and psychiatric care providers who administered the intervention. All participants provided written informed consent prior to enrollment. This study is registered in the

UMIN Clinical Trials Registry (UMIN000036017). The protocol of the trial, details of the intervention, and main trial findings were reported elsewhere.[10, 11] Therefore, the method of the trial is described briefly.

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

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

2.2 Cancer screening program provided by the municipality

In Japan, the Ministry of Health, Labour and Welfare (MHLW) recommends population-based cancer

screening for colorectal, gastric, lung, breast, and cervical cancer. These screenings are provided by local governments with a low co-payment. In this study, we recommended colorectal cancer screening using the FOBT for individuals aged 40 years and older. The cancer screening program of Okayama City does not mail the FOBT kit in advance. Instead, individuals select a clinic offering cancer screening and make an appointment to visit the clinic to receive the kit. Although individuals with a low household income can receive free screening, eligible individuals must apply for a coupon in advance at the municipal office.

The Okayama municipal government distributes a leaflet and detailed brochure encouraging participation in the above cancer screening program to all households in the city once a year.

2.3 Case management intervention to encourage participation in cancer screening

A case manager (nurse or psychiatric social worker) provided three counseling sessions to the study participants allocated to the CM plus TAU group. The CM intervention aimed to educate and navigate patients around colorectal cancer screening.

The first session, which was conducted in person, comprised the following components: a) education on the importance and content of colorectal cancer screening, using a pamphlet, b) assistance in making decisions and an appointment for colorectal cancer screening, and c) assistance in obtaining a coupon for free screening, if necessary. Other cancer screening was also briefly

mentioned using the pamphlet. Education on cancer screening using the pamphlet did not take the approach whereby the seriousness or severity of cancer was emphasized.

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

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

2.4 Follow-up interview conducted after the end of the intervention period

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

2.4.1 Interviews with patients

In a structured interview, the case manager asked the CM plus TAU group participants about "patients' acceptability of the intervention," "helpful components of the intervention," and "reasons for participation or non-participation in cancer screening."

For *patients' acceptability of the intervention*, patients were asked about "affective attitude," which is one of the components of the theoretical framework of acceptability.[14] This theoretical framework was developed according to the overview of systematic reviews focusing on patients' acceptability of healthcare interventions.[14] We selected the affective attitude that was considered most helpful in disseminating the intervention. Patients were asked, "how do you feel about this recommendation for cancer screening?"

For *helpful components of the intervention*, patients were asked to describe the components of the intervention that they perceived as helpful. The interviewer categorized patients' open-ended responses into the following components of the intervention: assignment of a case manager; explanation of colorectal cancer screening; explanation of the coupon for free screening; planning a schedule for the cancer screening; and follow-up contact at a later date. Patients were asked, "what was helpful in this intervention?"

For *reasons for participation or non-participation in cancer screening*, patients were asked to describe their reasons for participation or non-participation with an open-ended question. The

interviewers categorized patients' responses into predetermined options, which were based on a Japanese public opinion survey on cancer control,[15] and were classified into the following categories based on the Health Belief Model: perceived susceptibility perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.[16] Patients were asked, "what were your reasons for participating or not participating in colorectal cancer screening?"

The interviewer summarized the content immediately after the responses were obtained, and the interviews with patients were not recorded.

2.4.2 Interviews with providers

A group interview was conducted with providers to assess the implementation outcomes of the intervention. Proctor et al. proposed the Implementation Outcomes Framework,[17] which conceptualizes the variables of interest in implementation evaluation. Among the implementation outcomes included in this framework, we investigated "acceptability," "appropriateness," and "feasibility," which were all measurable factors in this study.

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 validity of the results. For "patients' acceptability of the intervention," content analysis was performed on the patients' responses described by interviewers. The open-ended responses were coded following a discussion between two researchers (YY, a psychiatrist with 6 years of clinical experience, and TE,

a nurse with more than 10 years of clinical experience), and the number of responses was tabulated according to the codes created. For "helpful components of the intervention," "reasons for participation in cancer screening," and "reasons for non-participation in cancer screening," the open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers. Answers that did not fit into the predetermined options were coded by the same researchers, and the number of responses was tabulated according to the codes created. Responses to "patients' acceptability of the intervention" and "helpful components of the intervention" were stratified according to whether patients had received cancer screening.

For the data obtained from the interviews with providers, the researcher extracted and summarized the opinions obtained from the verbatim transcripts and asked the interviewees to revise and confirm the summarized descriptions.

2.6 Patient and public involvement statement

Patients were not directly involved in the development of the research questions and interventions or in the design of the planned study. We obtained patients' feedback regarding the intervention in this study. The results of the study will be published on our facilities' and funder's website.

3. RESULTS

3.1 Patient enrollment 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)
Age, years			
Median (range)	52 (39, 74)	54 (39, 80)	53 (39, 80)
Sex			
Women	37 (47.4%)	35 (46.7%)	72 (47.1%)
Educational level*			
≤ 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%)
Marital status*			
Married	9 (11.5%)	8 (10.7%)	17 (11.1%)
Living alone*			
Yes	39 (50.0%)	36 (48.0%)	75 (49.0%)
Current outpatient for physical illness*			
Yes	38 (48.7%)	35 (46.7%)	73 (47.7%)
History of receiving colorectal cancer screening*			
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%)
mGAF score			
Mean (SD)	49.6 (15.7)	50.9 (14.8)	50.2 (15.2)
Range	15, 85	25, 85	15, 85
Participation in colorectal cancer screening			
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%)

*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.

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

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. Content analysis was performed by the researchers, and the number of responses was tabulated according to the codes created.

†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 TAU 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

"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. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

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 TAU 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*

		Patients in CM plus TAU group who received cancer screening (N = 39)	
Categories	Patients' responses	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
	Because I had other physical illnesses.	3	7.7
Perceived benefit	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. 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 based on the Health Belief Model: perceived susceptibility; perceived severity; perceived benefits; perceived barriers; cue to action; and self-efficacy.

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

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

"I didn't receive it because I have good bowel movements." ID 67

"I didn't receive it because I had already had the screening before, and I thought I didn't need to take it again." ID 160

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

"I misunderstood the period during which the screening was conducted." ID 75

"I was going to see the doctor, but I forgot my coupon for free screening." ID 4

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
Content of free description**			
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. Open-ended responses obtained from the interviews were categorized into predetermined options by the interviewers, and the number of responses was tabulated.

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

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.

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

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

- 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.

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

"During the follow-up sessions, few patients changed their intentions of receiving/not receiving cancer screening or required additional support. Follow-up sessions may not be necessary for all patients." Psychiatric social worker, 25 years of clinical experience

In terms of "feasibility," the following comments were made:

"This intervention will take some getting used to but will not require time-consuming training sessions. Once explained, it is possible to carry out the intervention in accordance with the procedures." Psychiatric social worker, 25 years of clinical experience

"This intervention could be administered quickly for patients who have a history of undergoing cancer screening. As the number of those who have undergone cancer screening increases, the burden on case managers will be reduced." Psychiatric social worker, 25 years of clinical experience

"It is difficult to encourage all eligible patients for colorectal cancer screening at once in terms of human resources. The impact of the COVID-19 epidemic made it even more difficult." Nurse, 20 years of clinical experience

4. DISCUSSION

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

4.1 *Patients' acceptability and helpful components of the intervention*

From the patients' perspective, evaluations of the intervention were mostly positive, which suggested

that there is patient demand for this intervention. In addition, few patients, including those who did not receive colorectal cancer screening, reported any discomfort or anxiety about receiving the intervention. This suggests that this intervention method is acceptable to most patients.

Regarding the components of the intervention that were considered helpful, most patients reported that the explanation of the colorectal cancer screening process was helpful. Patients with schizophrenia have barriers to accessing and understanding information about cancer screening and those related to practical issues. [18-20] Moreover, many patients may not have been aware of the information distributed by the municipality (i.e., the leaflet and brochure) or understood the procedure to receive colorectal cancer screening. The present findings suggest that providing direct and individualized explanations is effective in addressing these barriers.

4.2 Reasons for participation or non-participation in cancer screening

The largest proportion of patients stated that being encouraged in this study was the reason for receiving cancer screening. This suggests that the CM intervention acted as an effective cue to undergo cancer screening. This is consistent with a previous finding that physicians' recommendation of screening is the strongest predictor of patients receiving cancer screening in those with psychiatric disorders.[21] Furthermore, as other reasons for receiving screening, numerous patients highlighted the desire for prevention/early detection of cancer and the low cost of cancer screening. This suggests

that the intervention was able to address the perceived benefits and barriers of patients with schizophrenia. Few patients responded that fear of cancer was the reason for undergoing colorectal cancer screening. This may be because the intervention did not emphasize the seriousness or severity of cancer. In addition, a significant number of patients answered that they underwent cancer screening because they had done so every year. Therefore, a simple intervention may be sufficient for such patients. It is essential to encourage patients to undergo consistent colorectal cancer screening every year.

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

4.3 Acceptability, appropriateness, and feasibility of the intervention from the providers'

perspective

The providers who provided the intervention evaluated it as an "acceptable" approach to encourage participation in cancer screening at the psychiatric outpatient clinic. Supporting the physical health of patients with mental illness was considered an important role of psychiatric outpatient clinics, and thus awareness of this issue should be raised within clinics when implementing the intervention.

It was also perceived as "appropriate" to provide patients with tailored navigation on cancer screening procedures. The CM intervention was considered appropriate because many patients reported that they were able to complete the procedure themselves after receiving the individualized intervention. Patient navigation has been gaining interest as an approach to reducing disparities in cancer screening and diagnosis.[22] This was an essential component of the CM intervention.

In this study, providers perceived that it was easy to understand the content of and administer the intervention. This suggests that it is likely to be "feasible" for implementing in routine clinical practice. However, there are also challenges to the implementation of the intervention in a clinical setting in terms of resources. In particular, providers considered it would be difficult to deliver the intervention to all eligible patients simultaneously. There are currently insufficient outpatient staff to provide interventions to the large number of outpatients who visit each day. Thus, it may be necessary to adopt strategies according to the resources available at each facility, such as providing the intervention initially to patients within reach and eventually to all individuals.

4.4 Limitations

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

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, including the development of educational methods for providers, is needed to implement this CM intervention in various psychiatric clinical settings.

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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. Masaki Fujiwara reports grants from the Japanese MHLW, received during the conduct of the study,

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Patient consent for publication

Not required.

Ethics approval

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

Data sharing statement

The datasets in this study are not publicly available because of the terms of consent to which the participants agreed but may be available from the corresponding author on reasonable request.

6. REFERENCES

1. Crump C, Winkleby MA, Sundquist K, et al. Comorbidities and mortality in persons with schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170(3):324–33. https://doi.org/10.1176/appi.ajp.2012.12050599.

2. Olfson M, Gerhard T, Huang C, et al. Premature mortality among adults with schizophrenia in

the United States. *JAMA Psychiatry* 2015;72(12):1172–81. https://doi.org/10.1001/jamapsychiatry.2015.1737.

3. Pettersson D, Gissler M, Hällgren J, et al. The overall and sex- and age-group specific incidence rates of cancer in people with schizophrenia: a population-based cohort study. *Epidemiol Psychiatr Sci* 2020;29:e132. https://doi.org/10.1017/S204579602000044X.

4. Zhuo C, Tao R, Jiang R, et al. Cancer mortality in patients with schizophrenia: systematic review and meta-analysis. *Br J Psychiatry* 2017;211(1):7–13. https://doi.org/10.1192/bjp.bp.116.195776.

5. Hwong AR, Mangurian C. Improving breast cancer screening and care for women with severe mental illness. *J Clin Oncol* 2017;35(36):3996–8. https://doi.org/10.1200/JCO.2017.76.0462.

6. Solmi M, Firth J, Miola A, et al. Disparities in cancer screening in people with mental illness across the world versus the general population: prevalence and comparative meta-analysis including 4 717 839 people. *Lancet Psychiatry* 2020;7(1):52–63. https://doi.org/10.1016/S2215-0366(19)30414-6.

7. Fujiwara M, Inagaki M, Nakaya N, et al. Cancer screening participation in schizophrenic outpatients and the influence of their functional disability on the screening rate: A cross-sectional study in Japan. *Psychiatry Clin Neurosci* 2017;71(12):813–25. https://doi.org/10.1111/pcn.12554.

8. Shin DW, Chang D, Jung JH, et al. Disparities in the participation rate of colorectal cancer screening by fecal occult blood test among people with disabilities: a national database study in South Korea. *Cancer Res Treat* 2020;52(1):60–73. https://doi.org/10.4143/crt.2018.660.

9. Fujiwara M, Higuchi Y, Nakaya N, et al. Trends in cancer screening rates among individuals with serious psychological distress: an analysis of data from 2007 to 2016 Japanese national surveys, *J Psychosoc Oncol Res Pract* 2020;2(3):e025. https://doi.org/10.1097/OR9.0000000000000025

10. Fujiwara M, Inagaki M, Shimazu T, et al. A randomised controlled trial of a case management approach to encourage participation in colorectal cancer screening for people with schizophrenia in psychiatric outpatient clinics: study protocol for the J-SUPPORT 1901 (ACCESS) study. *BMJ Open* 2019;9(11):e032955. https://doi.org/10.1136/bmjopen-2019-032955.

11. Fujiwara M, Yamada Y, Shimazu T, et al. Encouraging participation in colorectal cancer screening for people with schizophrenia: a randomized controlled trial. *Acta Psychiatr Scand* 2021;144(4):318–28. https://doi.org/10.1111/acps.13348.

12. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual 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. https://doi.org/10.3322/caac.21334.

20. Clifton A, Burgess C, Clement S, et al. Influences on uptake of cancer screening in mental health service users: a qualitative study. *BMC Health Serv Res* 2016;16:257. https:

//doi.org/10.1186/s12913-016-1505-4.

21. 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.

22. 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.

23. 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.

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*

		Patients in the TAU group who did not receive cancer screening (N = 65)	
Categories	Patients' responses	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
Content of free description**			
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
Other	Because I recently had a colonoscopy.	2	3.1
	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.

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

Reasons for non-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.

Standards for Reporting Qualitative Research (SRQR)*

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

	Page/line no(s).
Title and abstract	
Title - 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.1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	p.4, 5
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	p. 7, 8
Purpose or research question - Purpose of the study and specific objectives or questions	p. 8
Methods	
Qualitative approach and research paradigm - 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. 8, 9
Researcher characteristics and reflexivity - 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. 14
Context - Setting/site and salient contextual factors; rationale**	p. 9-11
Sampling strategy - 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. 9
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	p.8
Data collection methods - 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. 14, 15

Data collection instruments and technologies - 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
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	p. 15, 16
Data processing - 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
Data analysis - 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
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	p. 13-15

Results/findings

Synthesis and interpretation - 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
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic finSdings	p. 19-28

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - 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
Limitations - Trustworthiness and limitations of findings	p. 31, 32

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	p. 34, 35
Funding - 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.

**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
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