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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

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ABSTRACT

Introduction One of the reasons for the high mortality rate from cancer in people with schizophrenia is delay in diagnosis. Many studies have shown lower cancer screening rates in people with schizophrenia; however, there are no interventions for people with schizophrenia to increase cancer screening. Therefore, we developed a case management (CM) intervention to encourage participation in cancer screening. The purpose of this study was to examine the efficacy of CM to encourage participation in cancer screening for people with schizophrenia, with particular focus on colorectal cancer screening by faecal occult blood testing, compared with usual intervention (UI), namely, municipal public education.

Methods and analysis This is an individually randomised, parallel group trial with blinded outcome assessments. The participants will be randomly allocated to either the CM plus UI group or UI alone group in a 1:1 ratio using a web-based program at a data management centre. The primary end point of the study is participation in colorectal cancer screening in the year of intervention, which will be assessed based on municipal records.

Ethics and dissemination This study is performed in accordance with Ethical Guidelines for Medical and Health Research Involving Human Subjects published by Japan's Ministry of Education, Science, and Technology and the Ministry of Health, Labour, and Welfare and the modified Act on the Protection of Personal Information as well as the Declaration of Helsinki. 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). The findings of this trial will be submitted to an international peer-reviewed journal.

Strengths and limitations of this study

- This study is the first randomised controlled trial investigating the efficacy of an intervention for people with schizophrenia to encourage participation in cancer screening.
- The scope of this intervention must be feasible in daily clinical practice and be easy to implement.
- Our results will confirm only the effect of the intervention in a single year, although in Japan, colorectal cancer screening with faecal occult blood testing is recommended annually.
- This study will not evaluate the rate of follow-up colonoscopy for participants with a positive result on the faecal occult blood test, or the effect of the intervention on mortality.

Trial registration number UMIN000036017.

INTRODUCTION

Life expectancy in people with schizophrenia is 10–20 years shorter than for the general population,[1 2] and this mortality gap is a major public health concern. In people with schizophrenia, cancer is the second-leading cause of death after cardiovascular disease.[3 4] People with schizophrenia often have cancer risk factors such as poor lifestyle habits including high smoking rates.[5 6] Although the cancer incidence rates in people with schizophrenia are equal or lower than in those without,[7 8] a recent meta-analysis showed that

people with schizophrenia have a substantially greater risk of cancer mortality,[9] which suggests that they may have fewer opportunities to be screened and diagnosed with cancer. Therefore, cancer is an important physical comorbidity that causes a greater mortality in patients with schizophrenia.

To improve survival and quality of life in patients with schizophrenia and cancer, disparities in cancer care, including prevention, diagnosis, treatment, symptom management and end-of-life care, must be addressed.[10] Delayed cancer detection is one of the disparities in cancer care for patients with schizophrenia. Regarding breast cancer, patients with severe mental illness are likely to be diagnosed with a more advanced stage and with aggressive tumour characteristics.[11] Another study using a national inpatient database in Japan showed that patients with schizophrenia were likely to be admitted at a more advanced stage compared with those without psychiatric disorders.[12] Therefore, early detection of cancer in people with schizophrenia is an important public health issue.

However, a previous review has shown that there are lower cancer screening rates in people with mental illness.[13] Among patients with mental illness, patients with schizophrenia have been suggested to have a particularly low cancer screening rate.[14] Our previous study demonstrated that in Japan the colorectal cancer screening rate in people with schizophrenia was 24.1%, which is much lower than that of the general population at 40.7%.[15] In particular, people with schizophrenia who do not have the opportunity to participate in collective opportunistic cancer screening subsidised by insurers demonstrated extremely low colorectal cancer screening rates (13.4%).[16] However, to our knowledge, no interventions for people with severe mental illness have been implemented to increase cancer screening.[17]

In the general population, the Centers for Disease Control and Prevention recommend the following components to improve cancer screening rates: client reminders, small media, one-on-one education and multicomponent intervention.[18] For people with schizophrenia, implementing these components using an individualised multimodal case management approach is desirable, considering these patients' lesser ability to access such services and information. In psychiatric medical settings, multimodal case management such as planning and coordinating necessary services for community life is commonly implemented based on an individual assessment of each patient. Case management may also include advice on physical health and referral to appropriate specialists.

The purpose of the present confirmatory randomised controlled trial is to examine the efficacy of case management intervention to encourage participation in cancer screening, with particular focus on colorectal cancer screening, for people with schizophrenia.

METHODS

Trial design

This study is an individually randomised, parallel group trial with blinded outcome assessments (figure 1). Participants will be randomised to an intervention group to encourage participation in cancer screening, using case management (CM) plus usual intervention (UI) including municipal public education (CM plus UI group) or usual intervention alone (UI alone group).

Settings for cancer screening in Japan

Screening delivery system

In Japan, population-based cancer screening is provided by local governments.[19] These municipal cancer screening programmes are aimed mainly at unemployed people, employees of small-sized to medium-sized companies and the self-employed. Employees of large companies are expected to receive collective opportunistic cancer screening subsidised by insurers. The municipal cancer screening is a major cancer screening opportunity for people with schizophrenia, who have no opportunity to receive collective opportunistic cancer screening subsidised by insurers.

In municipal cancer screening programmes provided by Okayama City, which is the site of this study, individuals choose the clinic at which to receive cancer screenings from a list provided by Okayama City, and then make an appointment. Out-of-pocket costs are low, and are set by each municipality. In addition, individuals with low household income can receive screenings for free; however, individuals must apply for a free coupon in advance by visiting or calling a municipal office. In Okayama City, municipal cancer screening programme are annually provided from June to December.

Cancer screening programme

In Japan, the Ministry of Health, Labour, and Welfare (MHLW) recommends the following five cancer screening programmes[20]: annual faecal occult blood testing (FOBT) for colorectal cancer screening and chest X-ray for lung cancer screening for people aged ≥40 years[21]; biannual upper gastrointestinal X-ray or upper endoscopy for gastric cancer screening for people aged ≥50 years; biannual mammography for breast cancer screening for women aged ≥40 years and biannual Papanicolaou (Pap) smear testing for cervical cancer screening for women aged ≥20 years.

Intervention to encourage participation in cancer screening using case management

Nurses, psychiatric social workers or psychologists with at least 1 year of clinical experience, acting as case managers, will recommend colorectal cancer screening and support individual through these procedures (figure 2). During the first in-person interview for the intervention, all participants in the intervention group will be educated using a pamphlet, depending on the level of participants' understanding. The pamphlet includes the following

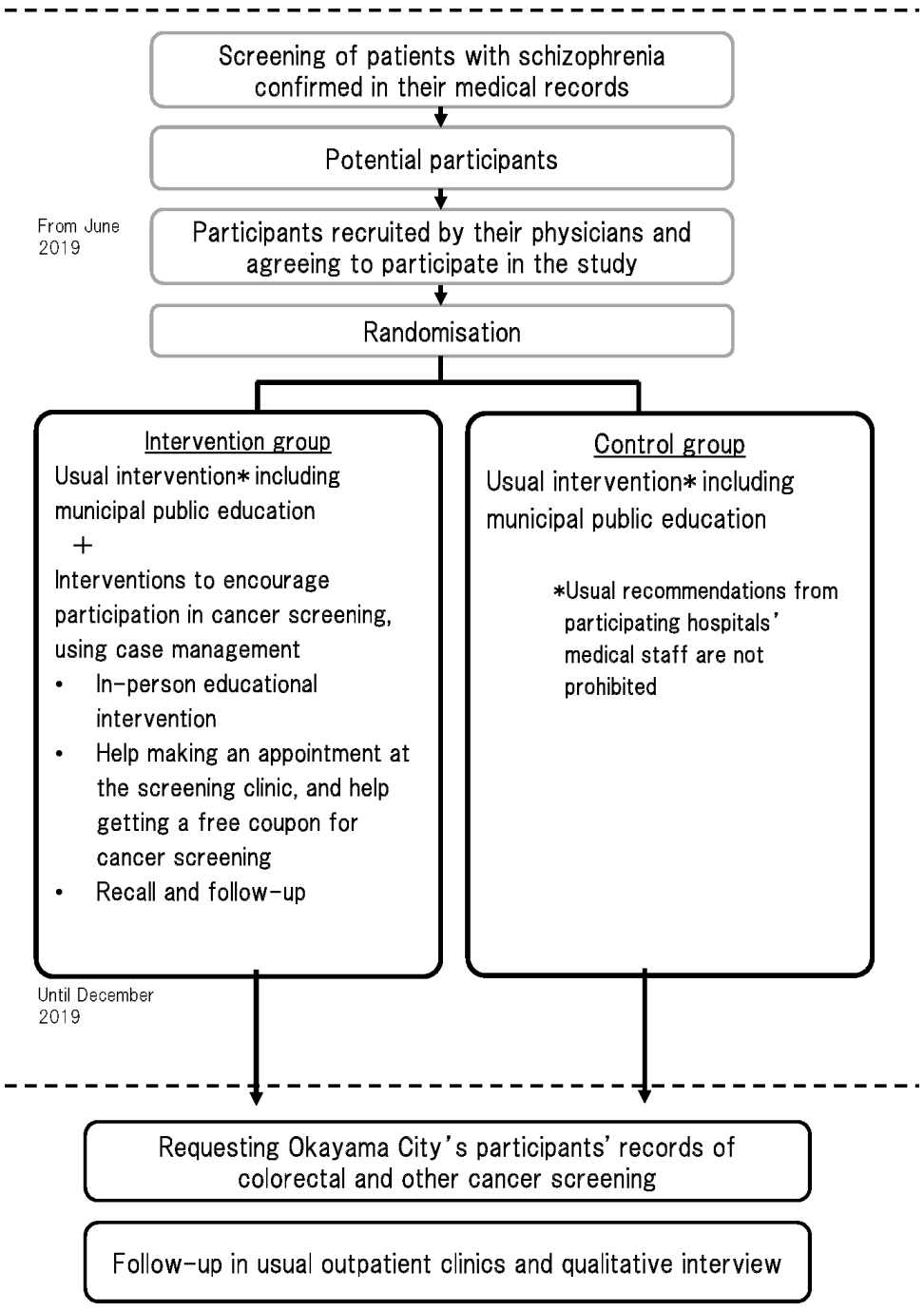

Figure 1 Study flow chart.

information: (1) cancer risk, (2) importance of early detection by cancer screening, (3) recommendation to undergo colorectal cancer screening, (4) information on how to proceed with colorectal cancer screening including (a) an appointment at a clinic, (b) monetary cost and the free coupon and (c) education on how to collect the sample for the FOBT. Then, participants' case managers will suggest clinics providing municipal cancer screening from the list provided by Okayama City, help participants schedule an appointment at the clinic and help obtain a free coupon according to the patient's mental symptoms, social functioning ability and living conditions. Colorectal cancer screening is the primary recommendation, although other cancer screenings are also recommended. The reasons for recommending primarily colon cancer screening by FOBT in this study is because this is the most highly recommended screening in Japan.[22]

In addition to the first-contact intervention, the case manager will recall and follow-up with participants by in-person interviews at least twice. If there is no opportunity for an in-person interview, case managers will call participants by telephone. During the interviews, the case managers will ask participants whether the procedure to receive colorectal cancer screening is going well. If participants have difficulty, the case manager will support participants to resolve the problem. If participants have received

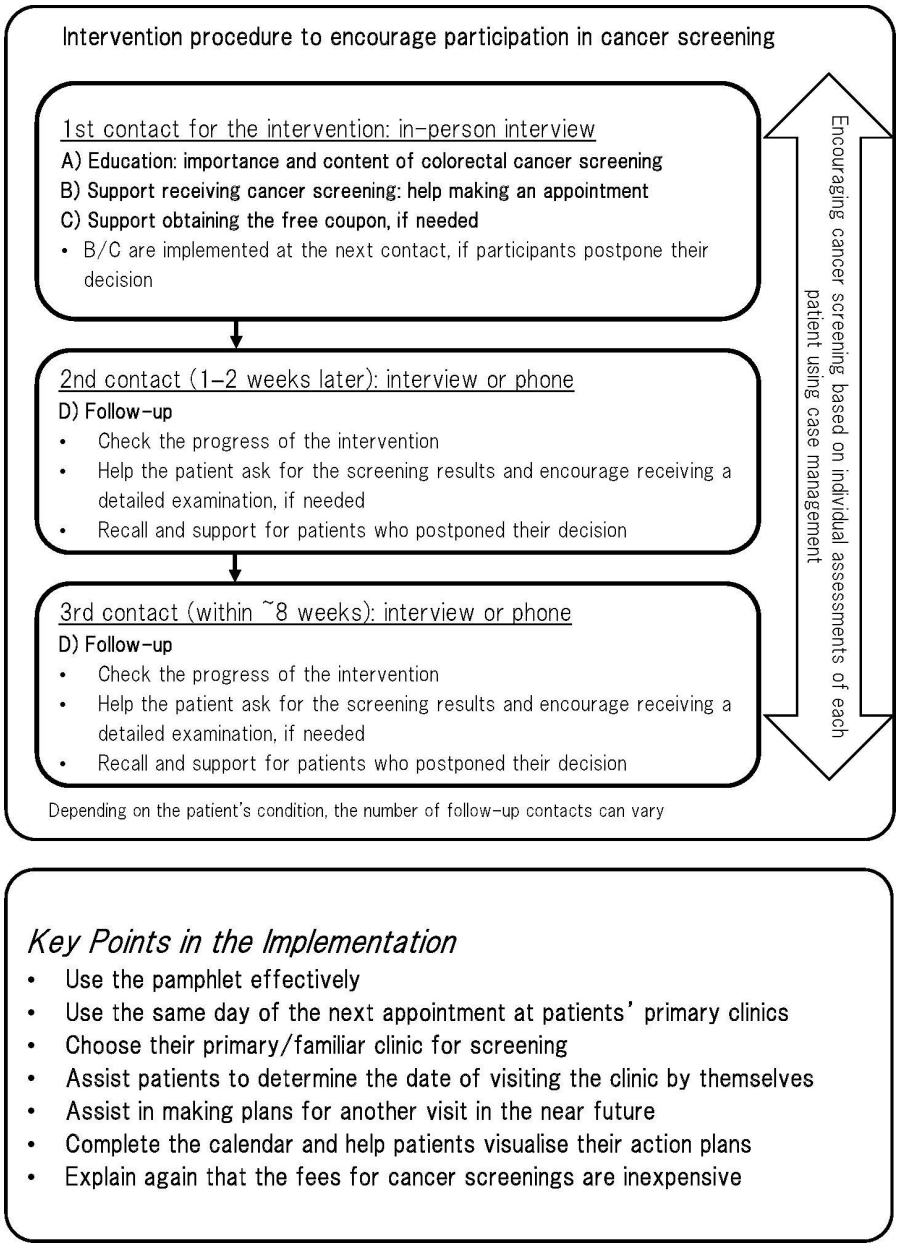

Figure 2 Procedure used in the intervention to encourage participation in cancer screening.

the screening, case managers will help participants obtain the screening results from the clinic. If participants have not undergone screening, the case manager will re-educate and support participants to receive cancer screening. Case managers can make further additional follow-up contacts if needed, or omit follow-up contacts based on their clinical assessment of the participants' functioning. In addition to these interventions, the following UIs will be offered.

Usual intervention including municipal public education

Usual recommendations, including those from hospital medical staff are not prohibited.

In addition, Okayama City provides public education to encourage cancer screening. Briefly, two documents are distributed to all households; one is a leaflet discussing the five cancer screening programmes recommended by the MHLW and the other is a detailed brochure for cancer screening programmes and other specific medical checkups that explains the criteria for participating, information on the free coupon and a list of commissioned clinics performing each screening and check-up. However, in Okayama City, regarding colorectal cancer screening, recalls are not performed for those who have not yet undergone screening.

Currently, encouraging participation to undergo cancer screening using case management is uncommon in psychiatric clinics. Therefore, distributing leaflets/brochures by the municipality is the only chance for people with schizophrenia to be encouraged to participate in cancer screening.

Case manager training

The intervention in this study was standardised in a manual with the goal that this intervention must be feasible within daily clinical practice. Nurses, psychiatric

social workers or psychologists with at least 1 year of clinical experience can implement the intervention in accordance with the procedures described in the manual that are within their clinical skills. Therefore, case managers do not require additional training for this intervention.

Setting

Participants in this study will be recruited from two psychiatric outpatient clinics: the Okayama Psychiatric Medical Center and the Jikei Hospital. The Okayama Psychiatric Medical Center (independent administrative institution with 252 beds and approximately 250 outpatient visits per day) is the core public psychiatric hospital in Okayama prefecture. The Jikei Hospital (570 beds and approximately 160 outpatient visits per day) is a large psychiatric hospital certified as a public-interest, incorporated, foundation. Both hospitals provide services ranging from outpatient psychiatric care to acute inpatient psychiatric care in this regional urban area.

Participants

The inclusion criteria are as follows: (1) patients are aged ≥40 years in the 2019 fiscal year in accordance with the recommendations for colorectal cancer screening by the MHLW,[20] (2) patients visiting the involved hospitals twice or more in the previous 6 months as their primary psychiatric outpatient service as of 1 April 2019; (3) patients who live in Okayama City and who are enrolled in the National Health Insurance or Public Assistance systems who have no opportunity to receive collective opportunistic cancer screening subsidised by insurers; (4) outpatients diagnosed by their current primary psychiatrist with schizophrenia or schizoaffective disorder based on their medical chart review and current/past psychiatric interviews according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition[23] and (5) patients who understand and agree to participate in this study by signing the informed consent form, or patients whose proxies consent to their participation in the study. The exclusion criteria are as follows: (1) patients with a history of colorectal cancer; (2) patients who have already participated in colorectal cancer screening in the 2019 fiscal year (municipal cancer screenings are provided between June and December, and people can receive one screening per fiscal year. Those who have already received cancer screening in the fiscal year 2019 before being recruited for the study will be excluded); (3) patients who plan to move out of Okayama City within 6 months; (4) patients who live in an institution where residents are supported for receiving cancer screening; (5) patients judged by their primary psychiatrists as having a risk of symptom deterioration if they participate in the study and (6) patients judged as having insufficient ability to make judgements on their own, by their primary psychiatrist, and who are not accompanied by their proxies when visiting clinics.

PROCEDURES

Participant recruitment

Eligible participants will be identified by their primary psychiatrists and referred to the research team. All participants are required to provide written informed consent before enrolment.

Case registration and randomisation using electronic data capturing

After obtaining consent, participants will be registered using an electronic data capturing (EDC) system. Immediately after registration, participants will be randomly allocated to either the CM plus UI group or UI alone group in a 1:1 ratio using permuted blocks and the EDC web program at the data management centre. Therefore, the random allocation will be concealed. Allocation will be stratified by facility and sex.

Intervention and observation period

The 2019 Okayama City cancer screening programme will occur from June to December; therefore, the intervention will be performed during the same period.

Concomitant treatment and care

There is no restriction on concomitant treatment and care. If the participants of the UI alone group wish to consult regarding cancer screenings, the medical staff will provide advice as usual.

Discontinuation of the protocol intervention for participants

The protocol intervention will be discontinued if a participant meets any of the following conditions: (1) the participant wishes to stop the protocol intervention; (2) primary psychiatrists or case managers judge that it is difficult to implement the protocol intervention because the participant's mental or physical symptoms worsen; (3) participants cannot be contacted and (4) the research team judges that it is inappropriate to implement the protocol intervention for any reason. Participants who discontinue the protocol intervention will be included in the intention-to-treat protocol.

Stopping the assessment

If a participant withdraws consent for screening record inquiry to the municipal screening database, the participant will be excluded from the intention-to-treat protocol. If a participant withdraws consent for follow-up interviews, the participant will not be followed. If consent for follow-up is withdrawn, but the participant does not withdraw consent for screening record inquiry, the participant will be included in the intention-to-treat protocol.

Qualitative follow-up interview

After the end of the period in which municipal cancer screenings are performed, follow-up interviews will be performed between January and March 2020. A structured interview to investigate the reasons for participation or non-participation in colorectal cancer screening and further detailed physical examinations will be performed

Table 1 Schedule of enrolment, interventions and assessments

	Enrolment	Allocation	Postallocation				Close-out
Timepoint	t0	t0	t1	t2	t3	Ongoing	
Eligibility screening	●						
Informed consent	●						
Participants' characteristic data	●						
Allocation		●					
Contact for intervention			●	●	●	If needed	
Assessment of harm			←	—	→		
Screening record inquiry							●
Qualitative follow-up interview							●

either in person or by telephone, as described in the Outcomes from the qualitative follow-up interviews and in table 1. In addition, we will also interview case managers regarding what was effective and what problems arose regarding participants' participation in colorectal cancer screening.

Data management, central monitoring, data monitoring and auditing

The data centre is located in the Department of Clinical Trial Data Management, Tokyo University Graduate School of Medicine, Tokyo, Japan. Data entry to the electronic case report form is performed by researchers using the EDC at each hospital. No personally identifiable information is entered into the EDC, and data centres do not collect personal information. Data management and central monitoring will be performed using the EDC web program Viedoc (Pharma Consulting Group, Uppsala, Sweden). There will be no data monitoring committee because this study's intervention to encourage participation in colorectal cancer screening is non-invasive and does not result in serious harm. Similarly, auditing is also not planned for this study.

Assessment measures

Table 1 shows the schedule for the outcome measurements.

Primary outcome measure

Participation in colorectal cancer screening organised by Okayama City in the 2019 fiscal year

We will examine participants' records of participation in colorectal cancer screening obtained from the Okayama City Health Center. As in our previous survey,[16] we submitted the list of participants (including each participant's name, date of birth, address and study identification number) to the Okayama City Health Center. This centre subsequently linked the participants' list with cancer screening records and then returned the list, after removing personally identifiable information.

Secondary outcome measure

Participation in other cancer screenings organised by Okayama City in the 2019 fiscal year

We will also examine participants' records of participation in other recommended cancer screenings. In Okayama City, according to the MHLW recommendations, lung, gastric, breast and cervical cancer screening are provided.

Outcomes from the qualitative follow-up interviews

The qualitative follow-up interview includes the following questions: (1) "Please tell us your reasons for participating or not participating in colorectal cancer screening", (2) "Please tell us your reasons for receiving or not receiving a detailed examination"; asked only of participants who answered that their FOBT result was positive; (3) "Please tell us about the results of the detailed examination and what followed"; asked only of participants who received a detailed examination. The following additional interview questions will be asked of participants in the intervention group: (4) "Please let us know how you feel after you were encouraged to participate in cancer screening" and (5) "Which points were helpful in the explanation or support you received in this study?"

Time required for the intervention

As a measure of the cost of the intervention, the time required for each intervention will be recorded by case managers.

Variables

We will obtain the following participant background characteristic data: age, sex, health insurance, marital status, living alone or living with family, educational status, presence or absence of current visits to other outpatient clinics for physical illness, symptom severity and functional disability, and experience of participation in colon cancer screening.

Participants' symptom severity and functional disability will be assessed by the primary psychiatrists using the modified Global Assessment of Functioning (mGAF) scale.[24] The mGAF is based on psychological, social and

occupational functioning and is an observer-rated numerical scale with a score ranging from 1 to 100; lower scores reflect lower functioning. The mGAF was developed to improve the reliability and validity of the original GAF.[24] We will use the Japanese version of the mGAF, which has good reliability and validity,[25] and will record the mGAF scores over the previous month. To increase the feasibility of the study, the mGAF, which can be easily assessed, will be used. We will not use other core psychopathology measures and more specific measures of functional outcomes so as not to decrease study participation rate.

Harms

This intervention encourages cancer screening, which can be implemented in daily clinical practice, and is not invasive. Therefore, no specific or serious adverse events are expected to occur in participants in this study. However, a participant's condition may deteriorate regardless of the intervention during the intervention period. We will receive a report from participants' primary psychiatrists for the following: (1) deteriorating condition requiring psychiatric hospitalisation and (2) participants for whom it is desirable to discontinue study participation for any reason (eg, deterioration of the relationship).

Data analysis

Analysis set

The full analysis set includes all participants meeting eligibility criteria who are assigned to a study group, but excludes participants who completely withdraw consent. Participants withdrawing consent to use their records from the municipal cancer screening programme will be excluded from the primary endpoint analysis as missing primary outcome data.

Primary analysis

We will use the χ^2 test under the null hypothesis that the proportion of participants who participate in colorectal cancer screening is the same between the CM plus UI group and UI alone groups. We will calculate a χ^2 statistic and p value. The distribution of severity will be described before unblinding the trial data, and if the number of cases in groups stratified by severity is adequate, the Cochran-Mantel-Haenzel test will be considered according to the severity. In addition, we will perform a subgroup analysis for each of the following variables: sex, marital status, living alone or living with family, educational status, presence or absence of current visits to other outpatient clinics for physical illness, experience of participation in colon cancer screening, and symptom severity and functional disability.

Secondary analysis

The χ^2 test will be performed under the null hypothesis that the proportion of participants who participate in other cancer screenings recommended for participants is the same between the CM plus UI group and UI alone group. Other cancer screenings will include gastric, lung, breast, and cervical cancer screening.

We will describe and evaluate the outcomes from the qualitative follow-up interviews and record the time taken for the intervention.

Sample size estimation

According to the results of our previous study,[16] the colorectal cancer screening rate in the current study population is 13.4%, and the goal of the intervention is to reach 40% participation, which is equivalent to that for the general population. Considering the effect of cointerventions, the colorectal cancer screening rate for the UI alone group is estimated to be 20%. To detect differences with a significance level of α=0.05 and a power of 80% with a two-tailed test, we calculate that at least 82 participants per group are required. We set the target number of participants at 172, assuming that 5% of the participants in each group will withdraw their consent or cannot be evaluated.

Study period

The study period of this trial will be from 1 June 2019 to 31 March 2021; the participant entry period will be 1 June 2019 to 31 December 2019. The participant entry period corresponds to the period during which the municipal cancer screening will be provided by Okayama City in the 2019 fiscal year.

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 using a survey performed in the pilot study examining the planned study's feasibility. We included the key points, regarding implementing the intervention that we obtained from the feedback, in the intervention manual for the planned randomised study. Patients will not be involved in recruitment or performing the study. The results of the study will be published on our facilities' and funder's website.

ETHICS AND DISSEMINATION

Research ethics approval

This study is performed in accordance with the Ethical Guidelines for Medical and Health Research Involving Human Subjects published by Japan's Ministry of Education, Science, and Technology and the MHLW, and the modified Act on the Protection of Personal Information as well as the Declaration of Helsinki. Potential participants or their proxies will be informed that they may refuse to participate or withdraw from the study at any time after providing informed written consent.

If important protocol modifications are needed, the researchers will discuss these and obtain ethics committee approval for the revised protocol.

Ancillary and post-trial care

Participants whose cancer screening results are positive will be supported in receiving detailed examinations and treatment as usual care.

Access to data

The data manager will transfer the final data set to the person responsible for statistical analysis.

Dissemination policy

The results will be submitted for publication in a peer-reviewed journal and will be presented at conferences. The protocol paper and the main paper analysing and discussing the results will be submitted to a peer-reviewed journal. The first author will be a member of the steering committee, and the coauthors will be determined before submitting each paper.

A pilot study investigating the feasibility of the intervention

To assess the feasibility of the intervention, we performed a single-arm pilot study among participants with schizophrenia in the same psychiatric outpatient clinics that will participate in the planned randomised study (UMIN000033849) from October to December 2018. Thirteen participants (six women) participated in the pilot study, and participant's average age was 56 years (range: 43–69 years). Ten (77%) participants had never undergone colorectal cancer screening. Case managers were able to perform in-person interviews with each participant on the first day of the intervention. As a result, participants received assistance from case managers to obtain the free coupon and in selecting a clinic and making an appointment for colorectal cancer screening. Case managers could follow participants, check their progress and assist participants with their procedures, in accordance with the intervention manual. The new information obtained from the pilot study was added to the intervention manual for the planned randomised study. The colorectal cancer screening rate of the participants in the pilot study in 2018 was 54% (7/13 participants), suggesting that the intervention might be effective and may increase the participation rate for colorectal cancer screening to match that of the general population.

DISCUSSION

To our knowledge, the present planned study is the first randomised controlled trial investigating the efficacy of intervention for people with schizophrenia, to encourage participation in cancer screening. Psychiatric outpatient clinics are considered one of the best settings for an individualised approach for people with schizophrenia because patients are followed by their primary psychiatrists, with whom they have an established relationship. The scope of the current intervention, case management to encourage participation in cancer screening in psychiatric outpatient clinics, must be feasible and easy to implement in daily clinical practice. If the efficacy of this intervention is confirmed in this study, the intervention will have promising applicability, clinically.

The present planned study has some methodological limitations. First, subjects who withdraw consent to use their records from the municipal cancer screening programme will be excluded from the primary end point analysis, which could bias the results. Second, this study confirms only the effect of the intervention and only for a single year, although Japan's colorectal cancer screening with FOBT involves annual screening, and annual screening is required to reduce colorectal cancer mortality. However, it is unclear whether patients will continue to participate in colorectal cancer screening with this intervention. Once the effect of this intervention has been confirmed, further follow-up studies are needed. Third, this study will not determine the rate of follow-up colonoscopy for participants with a positive FOBT result. There is no registry system to follow-up individual patients, and it is difficult to track individual medical use data in the Japanese health system. Given the sample size in this study, only a small number of participants are expected to have a positive result. Colorectal cancer screening using the FOBT is effective only if the test-positive patients are followed by colonoscopy in a timely manner.[26] Even in the general population, a large proportion of individuals with a positive FOBT fail to receive follow-up colonoscopy within 1 year.[27] Patients with schizophrenia, who have barriers to access medical care, may be less likely to receive follow-up colonoscopy after a positive FOBT result. Therefore, this study cannot examine the effect on mortality and cost-effectiveness. Fourth, because this study is being performed at only two centres, generalisability is limited. Fifth, informed consent procedures themselves may have effects on participants' screening behaviours. This could increase the colorectal cancer screening rate for the UI alone group and underestimate the effect of the intervention. Finally, the applicability of our findings to countries with different healthcare systems is unknown.

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Contributors MI, MF, MK, TM and YY developed the intervention procedures, and YU, MF, TS and HT modified the intervention. MI, MF, TS, MK, RS, TM, YY, SH, MF, HT, NN, KK, TM, SH, KH, HO, YU and NY participated in the design of the study. SH played a primary role in designing the statistical analysis. TM played a primary role in designing the data management approach. MI and MF drafted the manuscript. All authors revised the manuscript and approved the final version.

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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 Jikei Hospital (approval number: 146gou-1-5) as well as by the J-SUPPORT Scientific Advisory Board.

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REFERENCES

1 Tiihonen J, Lönnqvist J, Wahlbeck K, *et al*. 11-Year follow-up of mortality in patients with schizophrenia: a population-based cohort study (FIN11 study). *Lancet* 2009;374:620–7.
2 Hjorthøj C, Stürup AE, McGrath JJ, *et al*. Years of potential life lost and life expectancy in schizophrenia: a systematic review and meta-analysis. *Lancet Psychiatry* 2017;4:295–301.
3 Crump C, Winkleby MA, Sundquist K, *et al*. Comorbidities and mortality in persons with schizophrenia: a Swedish national cohort study. *Am J Psychiatry* 2013;170:324–33.
4 Olfson M, Gerhard T, Huang C, *et al*. Premature mortality among adults with schizophrenia in the United States. *JAMA Psychiatry* 2015;72.
5 Brown S, Birtwistle J, Roe L, *et al*. The unhealthy lifestyle of people with schizophrenia. *Psychol Med* 1999;29:697–701.
6 de Leon J, Diaz FJ. A meta-analysis of worldwide studies demonstrates an association between schizophrenia and tobacco smoking behaviors. *Schizophr Res* 2005;76:135–57.
7 Li H, Li J, Yu X, *et al*. The incidence rate of cancer in patients with schizophrenia: a meta-analysis of cohort studies. *Schizophr Res* 2018;195:519–28.
8 Nielsen RE, Kugathasan P, Straszek S, *et al*. Why are somatic diseases in bipolar disorder insufficiently treated? *Int J Bipolar Disord* 2019;7.
9 Zhuo C, Tao R, Jiang R, *et al*. Cancer mortality in patients with schizophrenia: systematic review and meta-analysis. *Br J Psychiatry* 2017;211:7–13.
10 Irwin KE, Henderson DC, Knight HP, *et al*. Cancer care for individuals with schizophrenia. *Cancer* 2014;120:323–34.
11 Iglay K, Santorelli ML, Hirshfield KM, *et al*. Impact of preexisting mental illness on all-cause and breast cancer-specific mortality in elderly patients with breast cancer. *J Clin Oncol* 2017;35:4012–8.
12 Ishikawa H, Yasunaga H, Matsui H, *et al*. Differences in cancer stage, treatment and in-hospital mortality between patients with and without schizophrenia: retrospective matched-pair cohort study. *Br J Psychiatry* 2016;208:239–44.
13 Weinstein LC, Stefancic A, Cunningham AT, *et al*. Cancer screening, prevention, and treatment in people with mental illness. *CA Cancer J Clin* 2016;66:133–51.
14 Eriksson EM, Lau M, Jönsson C, *et al*. Participation in a Swedish cervical cancer screening program among women with psychiatric diagnoses: a population-based cohort study. *BMC Public Health* 2019;19:313.
15 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;71:813–25.
16 Inagaki M, Fujiwara M, Nakaya N, *et al*. Low cancer screening rates among Japanese people with schizophrenia: a cross-sectional study. *Tohoku J Exp Med* 2018;244:209–18.
17 Barley EA, Borschmann RD, Walters P, *et al*. Interventions to encourage uptake of cancer screening for people with severe mental illness. *Cochrane Database Syst Rev* 2016;9:CD009641.
18 Centers for Disease Control and Prevention. What works fact sheet: cancer screening - the community guide. Available: https://www.thecommunityguide.org/sites/default/files/assets/What-Works-Factsheet-CancerScreening.pdf [Accessed 3 Jul 2019].
19 Ministry of Health, Labour and Welfare. Cancer screening (in Japanese). Available: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000059490.html [Accessed 3 Jul 2019].
20 Ministry of Health, Labour, and Welfare. Items of cancer screening by municipalities (in Japanese). Available: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000059490.html [Accessed 3 Jul 2019].
21 Cancer Registry and Statistics. Cancer information service NCC, Japan. cancer registry and statistics (in Japanese). Available: https://ganjoho.jp/reg_stat/index.html [Accessed 3 Jul 2019].
22 Cancer Screening Assessment and Management Division, Research Center for Cancer Prevention and Screening, National Cancer Center. Summary of recommendations on cancer screening guidelines (in Japanese). Available: http://canscreen.ncc.go.jp/guideline/matome.html [Accessed 3 Jul 2019].
23 American Psychiatric Association. *Diagnostic and statistical manual of mental disorders (DSM-5®*. Washington, DC: American Psychiatric association Publishing, 2013.
24 Hall RC. Global assessment of functioning. A modified scale. *Psychosomatics* 1995;36:267–75.
25 Eguchi S, Koike S, Suga M, *et al*. Psychological symptom and social functioning subscales of the modified global assessment of functioning scale: reliability and validity of the Japanese version. *Psychiatry Clin Neurosci* 2015;69:126–7.
26 Tiro JA, Kamineni A, Levin TR, *et al*. The colorectal cancer screening process in community settings: a conceptual model for the population-based research optimizing screening through personalized regimens Consortium. *Cancer Epidemiol Biomarkers Prev* 2014;23:1147–58.
27 Martin J, Halm EA, Tiro JA, *et al*. Reasons for lack of diagnostic colonoscopy after positive result on fecal immunochemical test in a safety-net health system. *Am J Med* 2017;130:93.e1–93.e7.