



**Effect of Stamped Reply Envelopes and Timing of Newsletter
Distribution
Comparison of Response Rates with Random Allocation
in The Japan Nurses' Health Study**

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Effect of Stamped Reply Envelopes and Timing of Newsletter Distribution Comparison of Response Rates with Random Allocation in The Japan Nurses' Health Study

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Abstract

11 **Objective** To examine whether and how stamped reply envelopes as compared to business reply
12 envelopes and the timing of newsletter distribution affect the odds of response.

13 **Design** A randomized controlled trial in a prospective cohort study, estimating response rates associated
14 with enclosure of different types of reply envelope and timing of newsletter delivery.

15 **Setting** The Japan Nurses' Health Study (JNHS) consists of a cross-sectional baseline survey that includes
16 a 6-year entry period, from 2001 to 2007 and a 10-year follow-up study, from 2001 to 2017. The baseline
17 survey includes approximately 50,000 responses from participants in Japan. Among them, approximately
18 16,000 women participated in the follow-up survey.

19 **Participants** The present study included 6,938 women who were part of the first-year entry cohort for the
20 fifth wave of the biannual follow-up survey of the JNHS.

21 **Intervention** To estimate the effect of type of return envelopes and timing of newsletters, participants in
22 the present study were randomly allocated into four groups. For Groups 1 and 2, business-reply return
23 envelopes were enclosed, and for Groups 3 and 4, stamped return envelopes were provided. Also, for
24 Groups 1 and 3, a newsletter was enclosed when the questionnaires were mailed out; for Groups 2 and 4,
25 newsletters were sent with thank-you and reminder letters. The thank-you and reminder letters were
26 mailed out to all respondents at the end of the sixth week. This study was censored at the end of 12 weeks.

27 **Main outcome measures** For the pre-reminder analysis (first 6 weeks), the main outcome measures were
28 response rates and response time from mailing out questionnaires to receiving the self-administered
29 questionnaire; for the pre- and post-reminder analysis (entire 12-week study), the main outcome variable
30 was the likelihood of returning the questionnaire.

31 **Results** Pre-reminder analysis revealed that provision of stamped return envelopes increased the odds of
32 returning self-administered questionnaires, whereas provision of a newsletter decreased it. Compared with
33 participants in Group 1, who received business-reply envelopes and newsletters, participants in Group 4,
34 who received stamped return envelopes and no newsletters, were 42% more likely to return the
35 questionnaire. Pre- and post-reminder analysis demonstrated that newsletter delivery with reminder letters
36 decreased the probability of women's response rate by 22% relative to initial delivery with questionnaires.

37 **Conclusions** The style of return envelope affected response rates of mail-survey. The results of this study
38 indicated that while newsletter delivery in the initial packet generally lowered women's response rates for
39 survey questionnaires, a later delivery further decreased their response rate. These results suggest that
40 practices of provision of information should be handled individually, as a separate event from sending
41 follow-up questionnaire or reminder letters.

INTRODUCTION

The Japan Nurses' Health Study (JNHS) is a nationwide prospective occupational cohort study to explore women's health in Japan¹. The JNHS was designed as a prospective study, which consists of a cross-sectional baseline survey that includes a 6-year entry period from 2001 to 2007, and a 10-year follow-up study, from 2001 to 2017. For the follow-up study, 14,844 women agreed to participate in and signed an informed consent form¹.

For a prospective cohort study, maintaining the cohort, that is, maintaining high follow-up response rates is a major issue. A cohort study is used to estimate risks, rates, or occurrence times of events, and thus requires that the whole cohort remain under observation for the entire follow-up period². Loss of subjects during the study period lowers the validity of the study, because it makes estimation more difficult due to unknown outcomes of lost subjects. Prospective cohort studies that take many years are likely to experience difficulties with locating people over the study period². Follow-up studies that maintain less than about 60% of subjects are considered insufficient to provide confident estimates².

In an effort to achieve high response rates, offering incentives to respondents has become prevalent. A systematic review of 292 surveys showed that both monetary and non-monetary incentives improved the odds of returning the questionnaire³. Also, prior studies reported that the odds of receiving responses were increased when post-office stamped reply envelopes were used compared with enclosing pre-paid business reply envelopes³, although the results were mixed.⁴ Furthermore, sending advance letters has been shown to increase response rates, as well as providing follow-up contacts such reminder letters, telephone contacts, and providing nonrespondents with a second copy of the questionnaire^{3,5,6,7}. In addition, a study has reported that sending a cover letter that asks recipients to decline participation within 7 days if they do not want to participate, raises response rates⁸. Yet, using information leaflets upon recruitment did not affect the number of participants in the survey⁹.

As far as the JNHS is concerned, follow-up questionnaires are mailed to the cohort along with a newsletter. The newsletters are designed to update participants on new information about women's health and the progress of the JNHS. Women who do not respond to the first mailed questionnaire receive a second mailing within 6 months. Subsequently, women who still do not respond receive a third and fourth questionnaire. If the JNHS coordination center cannot contact participants by mail, the JNHS Follow-up Committee confirms if the subject has moved, and a questionnaire is sent to the new address, which is obtained from the resident registry of the corresponding local district.

In the present study, drawing on data from the fifth wave of the JNHS, we examined whether and how stamped reply envelopes compared to business reply envelopes and the timing of newsletter delivery affected the odds of a response. In Japan, studies that receive public funds are not allowed to offer incentives or stamped reply envelopes to survey participants as participants may not respond, and such a practice is regarded as a waste of research expenses for a study supported by the national government. However, for the JNHS it is expected that the use of stamped envelopes and delivery of a newsletter will

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4 have favorable effects on response rates. It is hoped that because the present study population draws from
5 a homogeneous cohort consisting of healthcare professionals, information regarding women's health in
6 general and results of previous JNHS surveys would encourage participant involvement in the study.
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8 **METHODS**

9 **Sample and Data**

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11 The present study included 6,938 women who were in the first-year entry cohort for the
12 fifth-wave follow-up survey of the JNHS. To estimate the effect of types of return envelope and timing of
13 newsletters, women were randomly allocated into the four groups shown in Table 1. For Groups 1 and 2,
14 business-reply return envelopes were enclosed, and for Groups 3 and 4, stamped return envelopes were
15 provided. In terms of timing of newsletter delivery, for Groups 1 and 3, the newsletter was enclosed when
16 the questionnaires were mailed out; for Groups 2 and 4, the newsletters were sent with the reminder letters.
17 The questionnaires were mailed to participants on December 22, 2009, and a thank-you or a reminder
18 letter was mailed out to all respondents (regardless of whether they had already returned their
19 self-administered questionnaires to the data center) at the end of the sixth week (February 2, 2010). The
20 present study was censored at May 16, 2010 (12 weeks or 84 days).
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23 **Statistical Analysis**

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25 The present study aimed to investigate the effect of type of return envelope and timing of
26 newsletter provision on participants' response rates in a follow-up survey. For this purpose, we examined
27 whether and how the type of return envelope (stamped vs. business reply) and timing of newsletter
28 provision (1st week vs. 6th week) affected the odds of returning the self-administered follow-up
29 questionnaire. We started with a descriptive analysis that provided an overview of women's responses to
30 the JNHS questionnaires. Then, we conducted a multivariate analysis that consisted of two parts. The
31 denominator of the analysis was all participants (6,938 women) for both parts; however, each analysis
32 focused on different time periods of the survey. First, we conducted a survival analysis for first 6 weeks
33 (before mailing out reminder letters). In the analysis for this period, it was assumed that the study was
34 censored at the 42nd day (the end of the sixth week) before distribution of reminder letters. Namely,
35 non-responders by the end of the sixth week were considered as censored at that time point. We analyzed
36 factors that affected response time (from mailing out questionnaires to receiving the self-administered
37 questionnaire), applying Cox's proportional hazard model. In the second part of the analysis, we analyzed
38 the effect of timing of newsletter delivery on the odds of returning the questionnaires for the entire study
39 period (i.e., 12 weeks). For all statistical analysis, SAS Ver. 9.1 (SAS Institute, North Carolina, USA) was
40 used and $p < 0.05$ was set as statistically significant.
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44 **Measurements** Response time was measured by the number of days between the day on which
45 the questionnaires were mailed out and the day on which the self-administered questionnaires were
46 received. Two relevant test variables in this analysis were the type of return envelope and the timing of the
47 newsletter delivery. With the questionnaires, 3,455 women received business-reply return envelopes, and
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3,483 women were provided with stamped return envelopes. For those who received stamped envelopes, the variable of *stamp* was coded as 1; otherwise, it was coded as 0. With respect to timing of newsletter delivery, if a newsletter was mailed with the initial letter and questionnaire, the variable of *newsletter_initial* was coded as 1; otherwise (i.e., newsletters were received with reminder letters), it was coded as 0. In contrast, if the newsletter was mailed with the reminder letter, then the variable of *newsletter_reminder* was coded as 1; otherwise (i.e., newsletters were already received with initial letters), it was coded as 0. Besides these two variables, following variables were included as potential confounders: age at the survey, type of nursing license (public health nurse, midwives, registered nurse [ref.], and licensed nurse), participation in previous surveys (Waves II, III, and IV), work status (not working vs. working [ref.]), and health status (regarding pregnancy, menopause, smoking, and drinking) in the previous survey, region of residence (Hokkaido [ref.], Tohoku, Kanto, Hokuriku_Koshin, Tokai, Kinki, Kyugoku, Shikoku, Kyusyu, or Okinawa), and type of residence area (urban vs. not-urban area).

RESULTS

Descriptive Analysis

Figure 1 shows unadjusted cumulative response rates by type of enclosed return envelope and timing of newsletter delivery. Before delivery of the reminder letters, cumulative response rates for women who received stamped reply envelopes (Groups 3 and 4) appeared to be higher compared with the rates for those who received business-reply envelopes (Groups 1 and 2). After distribution of the reminder letters, this tendency was retained. With respect to the effect of newsletter, when the newsletter was delivered at the beginning of the study, it had little influence on the response rate; when the newsletter was delivered with the reminder letter, it appeared to decrease the response rate. The response rates for Group 3 (newsletter provided at the beginning of the study) exceeded those for Group 4 (newsletter provided 6 weeks later with reminder letters) at Week 7 (in Figure 1); the response rates for Group 1 surpassed those for Group 2.

With respect to unadjusted cumulative response rates (results were not shown), Group 3 was highest (62.6%), rates for Groups 4 and 1 were in the middle, and the rate for Group 2 was lowest (56.1%). Among women who returned the questionnaire, those in Group 4 provided their self-administered questionnaires within the shortest time (28 days), whereas those in Group 1 had the longest response time (33 days). Women who received stamped return envelopes were more likely than those who received business reply envelopes to return the self-administered questionnaires. As for response time, women who received a newsletter with a reminder letter seemed to respond quickly, compared with those who obtained the newsletter at the beginning. However, considering that women who responded to the questionnaires tended to return them before the reminder letter, this result may suggest that newsletter delivery could serve to delay women's responses.

Multivariate Analysis

Period: Pre-reminder (1-6 weeks)

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First, we focused on the pre-reminder period (week 1 to week 6) to investigate whether and how the type of return envelope and delivery of newsletter affected response rates.

Table 2 presents regression coefficients and hazard ratios obtained from models predicting days for returning the questionnaires for the period before delivery of reminder letters. Multivariate model indicates that provision of a stamped return envelope increased the odds of returning the self-administered questionnaire by 17%. In contrast, provision of newsletters at the beginning decreased the probability of returning the questionnaires by 18%. The results of examination of survival curves using PROC LIFETEST in SAS (not shown) indicated that with respect to response time, women in Group 1 (business-reply envelopes; provided newsletters) took 28 days, on average, to return their questionnaire, whereas those in Group 4 (stamped return envelopes; not provided newsletters) took 24 days.

Period: Pre- and Post-reminder (1-12 weeks)

Next, focusing on the period of pre- and post-reminder (during the entire 12 weeks), we examined whether and how the timing of newsletter delivery affected the odds of returning the questionnaire among women who had not returned the self-administered questionnaire by the end of the sixth week. Reminder letters were mailed out to all participants at the end of the sixth week. Simultaneously, newsletters were distributed for those who did not receive them at the beginning of this study (i.e., Groups 2 and 4). Table 3 shows regression coefficients and odds ratios obtained from models predicting the odds of the returning the questionnaire for the period across (pre- and post-) the reminder delivery.

With respect to the effect of stamped return envelopes, the unadjusted effect was significant; stamped envelopes raised the odds of returning questionnaires by 9% relative to provision of business-reply envelopes. However, when adjusted for other relevant risk factors, the effect of stamped return envelopes became insignificant, as shown in Model 1. With respect to timing of newsletter distribution, Model 1 indicates that newsletter delivery with reminder letters decreased the probability of women's response to the survey by 22% relative to initial delivery with questionnaires. Model 2 shows that compared with women in Group 1, who received business-reply return envelopes and newsletters with the questionnaire, those in Group 2, who received business-reply return envelopes and were provided newsletters with reminder letters, were 23% less likely to return their self-administered questionnaire. In addition, women in Group 4 who obtained stamped envelopes and received newsletters with reminder letters were 17% less likely to return their self-administered questionnaire compared with women in Group 1. Taken together with results shown in Table 2 (newsletter provision decreased the odds of returning the questionnaire), these results suggest that while newsletter delivery in the initial packet generally lowered women's response rates to the questionnaire, later delivery decreased response rates even further.

CONCLUSION AND DISCUSSION

Results of the present study showed that provision of the newsletters with the questionnaires tended to decrease the odds of returning the self-administered questionnaire and extend the response time. In addition, if the newsletters were provided to participants 6 weeks later with reminder letters, it would further keep participants (non-responders at that point) from returning their questionnaires and prolong their response time. Thus, results suggest that each practice, such as provision of information, request for collaboration, and encouragement of contribution, should be managed individually, as separate events. As prior studies^{3,11} documented that advanced contacts via letters, cards, and phone calls increase the rates, if the update of the survey is offered via newsletter to respondents in advance, it may facilitate their understanding of the research issues and then improve response rates as well as enhance the quality of responses by reducing the number of items left blank or incomplete and decreasing inconsistent answers.

In the light of cost-performance, some studies suggest that allocating large sums of money to achieve high response rates may not always significantly improve the quality of the sample^{10, 11, 12}. Prior studies documented that with properly high response rates (approximately 70%), the bias due to non-response was unlikely to affect estimation of the survey^{10, 11, 12, 13}. However, for a follow-up cohort survey like the JNHS, maintaining high follow-up response rates is crucial to maintaining the cohort.

Provision of a stamped return envelope had a significant effect of raising the odds of returning the questionnaire in the JNHS follow-up survey. Although there is an argument that providing stamped return envelopes is an inappropriate use of research expenses (especially for research with public funds) and is not cost-beneficial, it depends on the survey response rates. If we assume provision of stamped return envelopes, compared to business-reply envelopes, increases the response rate by 10%, in a case survey of 10,000 participants, when the response rate is 50%, assuming that the stamped return envelope approach can improve the odds of response by 10%, the business-reply approach is better in terms of cost-performance. However, if the response rate is 80% in a survey of 10,000 participants, costs for the stamped return envelope approach and for business reply envelope approach will be 240,000 yen and 430,000 yen, respectively. Consequently, if the response rate is as high as 80%, the stamped return envelope approach will be more advantageous than the business-reply envelope approach in terms of cost-performance. In that case, providing stamped return envelopes is the best way for the JNHS to maintain the cohort with a better cost-performance.

In addition to the effect of the type of return envelope and timing of the newsletter, the present analysis showed interesting points with regard to factors predicting the response to the survey. Participation in a previous survey increased the odds of responding to this survey. In particular, participants who were involved in the most recent survey were 13 times more likely to return the questionnaire (as shown in Table 3). In addition, there appeared to be some differences in women's responses to the survey based on their residence regions. As shown in Table 3, women living in Hokkaido were more likely than those living in Kanto to respond to the survey. In contrast, women living in

Okinawa were less likely to respond to the survey; furthermore, Table 2 indicated that Okinawa women tended to take more time to return the self-administered questionnaire than those living in Kanto. Women who resided in Tohoku and Kyusyu also were more likely to take longer response time compared with those living in Kanto to respond to the survey.

Women who experienced pregnancy or menopause were more likely to participate in the present survey (shown in Tables 2 and 3). The questionnaire of the JNHS included several items with respect to pregnancy and menopause. Recognizing the association of the research issues with women's personal experiences would promote their involvement in the study. In contrast, smokers in the previous survey were less likely to respond to the present questionnaire. Given a recent negative image of smoking and the public trends against smoking, smokers would be reluctant to answer questions with regard to their health. However, if this tendency becomes prominent, health effects of smoking could be underestimated, especially in later surveys.

Limitations

There are several limitations to the present study. A major one refers to generalization of results. The cohort of the JNHS follow-up survey consists of female healthcare professionals with a nursing license who agreed to participate in the survey by signing an informed consent form. It may be problematic to apply the results of the present analysis to a broader population. There is, however, a major advantage of the present analysis. The JNHS is a nationwide occupational cohort study in Japan, and drawing on data from the cohort study, we could randomly allocate items of research interest, that is, type of return envelopes and timing of newsletter delivery, within the survey population.

Disclosure of Conflict of Interest The authors report no conflicts of interest.

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Table 1. Group allocation by type of return envelope and timing of newsletter delivery

| | | Return Envelope | Newsletter Delivery | |
|---------|---------------|--------------------|---------------------|-----------------|
| | | | Initial Letter | Reminder Letter |
| Group 1 | (n = 1,727) | business reply | enclosed | (not enclosed) |
| Group 2 | (n = 1,728) | business reply | (not enclosed) | enclosed |
| Group 3 | (n = 1,687) | stamped | enclosed | (not enclosed) |
| Group 4 | (n = 1,796) | stamped | (not enclosed) | enclosed |

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Figure 1 Cumulative Response Rates by Types of Return Envelope and Timing of Newsletter Delivery: Pre & Post Reminder

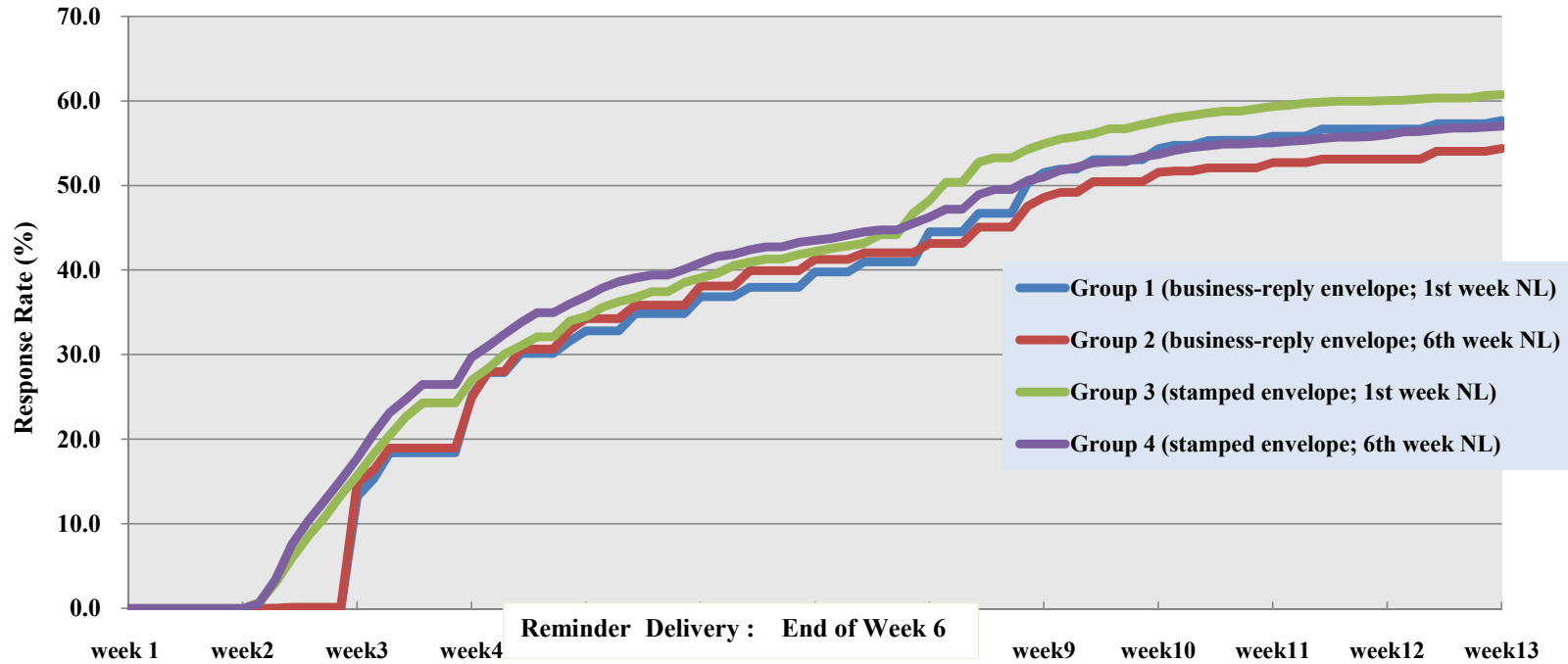


Table 2. Regression coefficients obtained from models predicting days for returning the questionnaires (pre-reminder)

| | Unadjusted | | | | Multivariate | | | |
|--|--------------|-----------|---|-------|--------------|-----------|---|-------|
| | Hazard Ratio | 95 % C.I. | | | Hazard Ratio | 95 % C.I. | | |
| Stamped return envelope (ref. Business-reply) | 1.074 | 1.243 | - | 1.155 | 1.167 | 1.080 | - | 1.262 |
| Newsletter initially enclosed (ref. Not | 0.770 | 0.891 | - | 0.828 | 0.823 | 0.762 | - | 0.889 |
| Age (in years @ Wave V) | 0.997 | 1.007 | - | 1.002 | 1.010 | 1.002 | - | 1.019 |
| Nursing License (ref. Registered nurse) | | | | | | | | |
| Public health nurse | 0.655 | 1.215 | - | 0.892 | 0.806 | 0.576 | - | 1.127 |
| Midwives | 1.014 | 1.310 | - | 1.152 | 1.139 | 0.995 | - | 1.303 |
| Licensed nurse | 0.837 | 1.131 | - | 0.973 | 1.002 | 0.851 | - | 1.181 |
| Participation in Previous Survey | | | | | | | | |
| Wave II (ref. not participated in Wave II) | 0.911 | 1.185 | - | 1.039 | 1.058 | 0.919 | - | 1.218 |
| Wave III (ref. not participated in Wave III) | 0.922 | 1.259 | - | 1.077 | 1.042 | 0.885 | - | 1.228 |
| Wave IV (ref. not participated in Wave IV) | 1.121 | 1.693 | - | 1.378 | 1.340 | 1.089 | - | 1.650 |
| In the previous survey | | | | | | | | |
| Not working (ref. working) | 0.889 | 1.181 | - | 1.025 | 1.045 | 0.897 | - | 1.217 |
| Pregnant (ref. Not-pregnant) | 0.603 | 1.253 | - | 0.869 | 0.994 | 0.680 | - | 1.452 |
| Experienced menopause (ref. Not experienced) | 0.903 | 1.049 | - | 0.973 | 0.848 | 0.747 | - | 0.962 |
| Smoking (ref. Not smoking) | 0.911 | 1.172 | - | 1.033 | 1.071 | 0.931 | - | 1.232 |
| # Drinking | 0.933 | 1.010 | - | 0.971 | 0.973 | 0.935 | - | 1.013 |
| Region (ref. Kanto) | | | | | | | | |
| Hokkaido | 0.682 | 1.176 | - | 0.895 | 0.844 | 0.627 | - | 1.136 |
| Tohoku | 0.679 | 0.901 | - | 0.782 | 0.772 | 0.664 | - | 0.899 |
| Hokuriku_Koshin | 0.800 | 1.036 | - | 0.910 | 0.946 | 0.824 | - | 1.087 |
| Tokai | 0.737 | 0.994 | - | 0.856 | 0.843 | 0.718 | - | 0.989 |
| Kinki | 0.722 | 0.938 | - | 0.823 | 0.851 | 0.741 | - | 0.978 |
| Cyugoku | 0.725 | 0.985 | - | 0.845 | 0.823 | 0.698 | - | 0.971 |
| Shikoku | 0.731 | 1.002 | - | 0.856 | 0.878 | 0.742 | - | 1.039 |
| Kjusyu | 0.670 | 0.872 | - | 0.764 | 0.741 | 0.643 | - | 0.853 |
| Okinawa | 0.339 | 0.735 | - | 0.499 | 0.524 | 0.352 | - | 0.780 |
| Area (ref. Non-urban) | | | | | | | | |
| Urban | 0.977 | 1.174 | - | 1.071 | 1.027 | 0.924 | - | 1.143 |
| Number of Observations Used | | | | | 3551 | | | |
| Likelihood Chi squared | | | | | 96.339*** | | | |

*** p < 0.001

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Table 3. Regression coefficients obtained from models predicting the likelihood of the returning the questionnaire (pre- and post- reminder)

| | Unadjusted | | | Multivariate | | |
|--|-------------|----------|----------|--------------|----------|----------|
| | odds ratio | 95% C.I. | | odds ratio | 95% C.I. | |
| Stamped return envelope (ref. Business-reply) | 1.104 | 1.004 | - 1.214 | 1.055 | 0.936 | - 1.189 |
| Newsletter_Reminder (ref. Initially provided) | 0.851 | 0.773 | - 0.936 | 0.784 | 0.695 | - 0.883 |
| Age (in years @ Wave V) | 1.021 | 1.014 | - 1.027 | 1.017 | 1.004 | - 1.030 |
| Nursing License (ref. Registered nurse) | | | - | | | - |
| Public health nurse | 1.658 | 1.059 | - 2.590 | 1.397 | 0.810 | - 2.410 |
| Midwives | 0.935 | 0.789 | - 1.107 | 0.851 | 0.692 | - 1.047 |
| Licensed nurse | 0.882 | 0.730 | - 1.065 | 0.934 | 0.727 | - 1.200 |
| Participation in Previous Survey | | | - | | | - |
| Wave II (ref. not participated in Wave II) | 1.776 | 1.505 | - 2.096 | 1.644 | 1.374 | - 1.969 |
| Wave III (ref. not participated in Wave III) | 3.812 | 3.230 | - 4.498 | 3.787 | 3.174 | - 4.519 |
| Wave IV (ref. not participated in Wave IV) | 12.959 | 10.840 | - 15.492 | 13.458 | 11.191 | - 16.185 |
| In the previous survey | | | - | | | - |
| Not working (ref. working) | 1.247 | 1.025 | - 1.519 | 1.219 | 0.950 | - 1.564 |
| Pregnant (ref. Not-pregnant) | 1.050 | 0.651 | - 1.694 | 2.172 | 1.126 | - 4.189 |
| Experienced menopause (ref. Not | 1.519 | 1.374 | - 1.680 | 0.917 | 0.754 | - 1.115 |
| Smoking (ref. Not smoking) | 0.624 | 0.536 | - 0.726 | 0.768 | 0.628 | - 0.941 |
| # Drinking | 0.967 | 0.920 | - 1.017 | 0.964 | 0.907 | - 1.025 |
| Region (ref. Kanto) | | | - | | | - |
| Hokkaido | 1.657 | 1.082 | - 2.538 | 2.275 | 1.258 | - 4.112 |
| Tohoku | 1.023 | 0.848 | - 1.234 | 1.018 | 0.803 | - 1.292 |
| Hokuriku_Koshin | 0.976 | 0.821 | - 1.161 | 0.942 | 0.757 | - 1.172 |
| Tokai | 1.029 | 0.842 | - 1.259 | 1.058 | 0.820 | - 1.365 |
| Kinki | 0.968 | 0.814 | - 1.150 | 1.071 | 0.861 | - 1.334 |
| Cyugoku | 0.967 | 0.790 | - 1.184 | 0.919 | 0.714 | - 1.183 |
| Shikoku | 0.977 | 0.794 | - 1.203 | 0.921 | 0.709 | - 1.196 |
| Kjusyu | 0.856 | 0.721 | - 1.015 | 0.849 | 0.686 | - 1.052 |
| Okinawa | 0.620 | 0.417 | - 0.923 | 0.787 | 0.482 | - 1.285 |
| Urban Area (ref. Non-urban) | 1.136 | 1.005 | - 1.285 | 1.034 | 0.876 | - 1.220 |
| Number of Observations Used | 6224 | | | | | |
| Likelihood Chi_squared | 1972.129*** | | | | | |

*** p < 0.001



Effect of stamped reply envelopes and timing of newsletter delivery on response rates of mail survey: A randomised controlled trial in a prospective cohort study

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|---------------------------------|--|
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Effect of stamped reply envelopes and timing of newsletter delivery on response rates of mail survey: A randomised controlled trial in a prospective cohort study

Abstract

Objective To examine the effects of stamped reply envelope and the timing of newsletter distribution.

Design A randomized controlled trial in a prospective cohort study with a 2x2 factorial design of two interventions.

Setting The Japan Nurses' Health Study (JNHS), a prospective cohort study for women's health.

Participants The present study included 6,938 women who were part of the first-year entry cohort for the fifth wave of the biannual follow-up survey of the JNHS.

Intervention The participants were randomly allocated into four groups; Group-1 (business-reply, newsletter with initial mailing), Group-2 (business-reply, newsletter with reminder), Group-3 (stamped envelopes, newsletter with initial mailing), and Group-4 (stamped envelopes, newsletter with reminder). The thank-you and reminder letters were mailed out at the end of the sixth week. This study was censored at the end of 12 weeks.

Main outcome measures Main outcome measures were cumulative response at the end of six and twelve weeks after mailing out the questionnaire.

Results The cumulative response at twelve weeks were 58.3% for Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 ($p=0.001$). The odds of the response was higher for stamped envelopes than for business-reply envelopes (OR [95%CI]=1.10[1.00-1.21]). The odds was higher for newsletter delivery with initial mailing than for with reminder (1.18[1.07-1.29]). The response in first six weeks for stamped envelope was significantly higher than for business-reply envelope ($p=0.047$). Although the response in six weeks for women received the newsletter with initial mailing was lower than for women who did not, the proportions did not differ significantly ($p=0.291$).

Conclusions The style of return envelope affected response rates of mail-survey. The results of this study suggest that practices of provision of the additional information, should be handled individually in advance, as a separate event from sending follow-up questionnaire or reminder letters.

INTRODUCTION

The Japan Nurses' Health Study (JNHS) is a nationwide prospective occupational cohort study to explore women's health in Japan¹. The JNHS was designed as a prospective study, which consists of a cross-sectional baseline survey that includes a 6-year entry period from 2001 to 2007, and a 10-year follow-up study, from 2001 to 2017¹. For a prospective cohort study, maintaining the cohort, that is, maintaining high follow-up response rates is a major issue. A cohort study is used to estimate risks, rates, or occurrence times of events, and thus requires that the whole cohort remain under observation for the entire follow-up period². Loss of subjects during the study period lowers the validity of the study, because it makes estimation more difficult due to unknown outcomes of lost subjects. Prospective cohort studies that take many years are likely to experience difficulties with locating people over the study period². Follow-up studies that maintain less than about 60% of subjects are considered insufficient to provide confident estimates².

In an effort to achieve high response rates, offering incentives to respondents has become prevalent. A systematic review of 292 surveys showed that both monetary and non-monetary incentives improved the odds of returning the questionnaire³. Also, prior studies reported that the odds of receiving responses were increased when post-office stamped reply envelopes were used compared with enclosing pre-paid business reply envelopes³, although the results were mixed.⁴ Furthermore, sending advance letters has been shown to increase response rates, as well as providing follow-up contacts such reminder letters, telephone contacts, and providing nonrespondents with a second copy of the questionnaire^{3,5,6,7}. In addition, a study has reported that sending a cover letter that asks recipients to decline participation within 7 days if they do not want to participate, raises response rates⁸. Yet, using information leaflets upon recruitment did not affect the number of participants in the survey⁹.

As far as the JNHS is concerned, follow-up questionnaires are mailed to the cohort along with a newsletter. The newsletters are designed to update participants on new information about women's health and the progress of the JNHS. Women who do not respond to the first mailed questionnaire receive a second mailing within 6 months. Subsequently, women who still do not respond receive a third and fourth questionnaire. If the JNHS coordination center cannot contact participants by mail, the JNHS Follow-up Committee confirms if the subject has moved, and a questionnaire is sent to the new address, which is obtained from the resident registry of the corresponding local district.

In the present study, drawing on data from the fifth wave of the JNHS, we examined whether and how stamped reply envelopes compared to business reply envelopes and the timing of newsletter delivery affected the odds of a response. In Japan, studies that receive public funds are not allowed to offer incentives or stamped reply envelopes to survey participants as participants may not respond, and such a practice is regarded as a waste of research expenses for a study supported by the national government. However, for the JNHS it is expected that the use of stamped envelopes and delivery of a newsletter will have favorable effects on response rates. It is hoped that because the present study population draws from

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3 a homogeneous cohort consisting of healthcare professionals, information regarding women's health in
4 general and results of previous JNHS surveys would encourage participant involvement in the study.
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8 **METHODS**

9 **Objectives**

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11 The primary objective of the study was to examine whether stamped reply envelopes and
12 enclosed newsletter improve response rates of mail survey by a 2x2 factorial randomised controlled trial in
13 the Japan Nurses' Health Study cohort. The secondary objective was to explore the demographic and
14 lifestyle factors that affect response rate of mail survey in a women cohort.
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17 **Participants**

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19 The JNHS consists of a cross-sectional baseline survey that includes a 6-year entry period, from
20 2001 to 2007 and a 10-year follow-up study, from 2001 to 2017. The study population was designed for
21 female registered nurse, licensed practical nurses, public health nurses, and/or midwives, who were at
22 least 30 years of age and resident in Japan. Although the participants were licensed to practice nursing,
23 they did not necessarily function as nurses. The baseline survey includes 49,927 responses from
24 participants in Japan. Among them, 14,844 women signed an informed consent form and participated in
25 the follow-up survey. Institutional review boards of Gunma University and the National Institute of Public
26 Health reviewed and approved the JNHS study protocol. The study design of the JNHS has been presented
27 elsewhere¹. The present study included 6,938 women who were in the first-year entry cohort for the
28 fifth-wave follow-up survey of the JNHS.
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34 **Intervention**

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36 To estimate the effect of types of return envelope and timing of newsletters, women were
37 randomly allocated into the four groups with a 2x2 factorial design. For Groups 1 and 2, business-reply
38 return envelopes for post-payment by the recipient were enclosed, and for Groups 3 and 4, stamped return
39 envelopes were provided. In terms of timing of newsletter delivery, for Groups 1 and 3, the newsletter was
40 enclosed when the questionnaires were mailed out; for Groups 2 and 4, the newsletters were sent with the
41 reminder letters. The questionnaires were mailed to participants on December 22, 2009, and a thank-you
42 and reminder letter was mailed out to all respondents, (regardless of whether they had already returned
43 their self-administered questionnaires to the data center) at the end of the sixth week (February 2, 2010).
44 The present study was censored at May 16, 2010 (12 weeks or 84 days). We did not perform any power
45 calculations based on primary hypothesis of this study.
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51 When the participants registered at baseline survey, the sequential unique 7-digit ID numbers
52 were assigned randomly by the JNHS data center. According to the ID numbers, participants were
53 allocated to the four groups. The allocated group number for each participant was the remainder when the
54 ID number was divided by four.
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57 **Measurements**

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Primary outcome measure was cumulative response proportion at 12 weeks after mailing out the questionnaire. Secondary outcome measure was cumulative response at the end of 6 weeks after initial mailing, just before delivering the reminder letters.

The participants were simultaneously randomised to two interventions: type of return envelope (business reply vs. stamped return envelopes) and timing of newsletter delivery (newsletter with initial mailing vs newsletter with reminder). Besides these two variables, following demographic and lifestyle variables were used to explore the factors affecting response rates: age at the survey, type of nursing license (registered nurse, licensed nurse, midwives, and public health nurse), region of residence (Hokkaido, Tohoku, Kanto, Hokuriku_Koshin, Tokai, Kinki, Cyugoku, Shikoku, Kyusyu, and Okinawa), and type of residence area (urban [Tokyo metropolitan area and other 19 large cities designated by government ordinance] and not-urban area), work status (not-working and working), smoking status (smoking and not-smoking), alcohol drinking (< 3 days a week and \geq 3 days a week), pregnancy (pregnant and not-pregnant), menopausal status (postmenopausal and others). All the data were obtained from the available latest wave of survey. These variables included factors previously studied^{10, 11, 12} and reproductive health related issues in women.

Statistical Analysis

Characteristics of participants were compared between groups using ANOVA and chi-square test to check the relevance of randomization process. Before examining main effect of two interventions, type of return envelope (business reply vs stamped) and timing of newsletter provision (with initial mailing vs. with reminder) on cumulative response proportion at 6 and 12 weeks after initial mailing, the interaction of these two interventions was tested by logistic regression model. The main effects of the interventions were tested by chi-square test. In order to examine the factors affecting the responses in 12 weeks after initial mailing, logistic regression models were used to estimate unadjusted and age-adjusted odds ratios (ORs) and their 95% confidence intervals (CIs). For all statistical analysis, SAS Ver. 9.1 (SAS Institute, North Carolina, USA) was used and $p < 0.05$ was set as statistically significant.

RESULTS

Characteristics of Participants

Of the 6938 women of the first-year entry JNHS cohort, 1727, 1728, 1687, and 1796 women were randomised into Group-1, Group-2, Group-3, and Group-4, respectively (figure 1). With the questionnaire, 3455 received business-reply return envelopes and 3483 women were provided with stamped envelopes. A total of 3414 women received the newsletter with initial mailing and 3524 women received the newsletter with thank-you and reminder mailing. The four groups did not differ significantly in demographic and lifestyle characteristics (table 1). Although there were slight differences among four groups in age at the survey ($p=0.081$) and menopausal status ($p=0.066$), no significant differences were found between any pairs of groups.

Cumulative response proportion by group

The cumulative response proportions at 12 weeks were 58.3% for women in Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 (figure 1), and these proportions significantly differed among the groups ($\chi^2=15.5$; d.f.=3; $p=0.001$). There was not statistically significant interaction effect of two interventions, type of enclosed return envelope and timing of newsletter delivery, on the proportions ($p=0.881$). The response for women who received stamped reply envelopes (Groups-3 and 4) was 58.6%, and it was significantly higher compared with the proportion of 56.2% for those who received business-reply envelopes (Groups-1 and 2) ($\chi^2=4.15$; d.f.=1; $p=0.042$). With respect to the effect of newsletter, the cumulative response proportion at 12 week when the newsletter was delivered at initial mailing was significantly higher than the response when the newsletter was delivered with thank-you and reminder letters ($\chi^2=11.1$; d.f.=1; $p<0.001$); 59.4% for Group-1 and 3 and 55.4% for Group-2 and 4.

We compared the cumulative proportions at 6 weeks to confirm the main effects of interventions without the effect of reminder mailing (figure 2). The proportion at 6 weeks for business-reply envelopes (Groups-1 and 2) was 40.3% and the proportion for stamped reply envelopes (Groups-3 and 4) was 42.7%, and those proportions differed significantly ($\chi^2=3.93$; d.f.=1; $p=0.047$). The proportion for women received the newsletter with initial mailing (Group-1 and 3) was 40.9% and the proportion for women who did not receive it with initial mailing (Group-2 and 4) was 42.1%, and these proportions did not differ significantly ($\chi^2=1.11$; d.f.=1; $p=0.291$).

Factors affecting response

The ORs and 95% CIs for cumulative responses at 12 weeks are shown in Table 1. With respect to two interventions, unadjusted ORs showed statistically significant effects. The stamped envelopes raised the response by 10% relative to provision of business-reply envelopes (OR [95%CI] = 1.10 [1.00 - 1.21]), and the newsletter delivery with initial mailing raised the response by 18% relative to the delivery with reminder letters (1.18 [1.07 - 1.29]). However, when adjusted by age at the survey, the effect of stamped return envelopes became not significant (table 2).

Regarding other factors that showed significant effects on the response by age-adjusted analyses, nursing license, region of residence, type of residence area, smoking, menopause, and participation in previous survey were associated with the odds of response.

DISCUSSION

Timing of newsletter delivery and type of return envelope

Results of the present study showed that provision of the newsletters with the questionnaires tended to decrease the odds of returning the self-administered questionnaire. In addition, if the newsletters were provided to participants 6 weeks later with reminder letters, it would further keep participants (non-responders at that point) from returning their questionnaires. Thus, the results suggest that each practice, such as provision of information, request for collaboration, and encouragement of contribution,

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3 should be managed individually, as separate events in advance. As prior studies^{3, 10, 14} documented that
4 advanced contacts via letters, cards, and phone calls increase the rates, if the update of the survey is
5 offered via newsletter to respondents in advance, it may facilitate their understanding of the research
6 issues and then improve response rates as well as enhance the quality of responses by reducing the number
7 of items left blank or incomplete and decreasing inconsistent answers.
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11 In the light of cost-performance, some studies suggest that allocating large sums of money to
12 achieve high response rates may not always significantly improve the quality of the sample^{13, 14, 15}. Prior
13 studies documented that with properly high response rates (approximately 70%), the bias due to
14 non-response was unlikely to affect estimation of the survey^{13, 14, 15}. However, for a follow-up cohort
15 survey like the JNHS, maintaining high follow-up response rates is crucial to maintaining the cohort.
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19 Provision of a stamped return envelope had a significant effect of raising the odds of returning
20 the questionnaire in the JNHS follow-up survey. Although there is an argument that providing stamped
21 return envelopes is an inappropriate use of research expenses (especially for research with public funds)
22 and is not cost-beneficial, it depends on the survey response rates that you expect to achieve. We should
23 discuss about the cost-performance based on the results of an actual cost analysis¹⁶. If we assume
24 provision of stamped return envelopes, compared to business-reply envelopes for post-payment by the
25 recipient, increases the response rate by 10%, in a case survey of 10,000 participants, when the response
26 rate with business-reply envelope is 50%, assuming that the stamped return envelope approach can
27 improve the odds of response by 10%, the business-reply approach is better in terms of cost-performance
28 (table 3). However, if the response rate is 80% in a survey of 10,000 participants, mailing costs for the
29 stamped return envelope approach and for business reply envelope approach will be 285 yen/response and
30 273 yen/response, respectively. Consequently, if the response rate is as high as 80%, the stamped return
31 envelope approach will be more advantageous than the business-reply envelope approach in terms of
32 cost-performance. In that case, providing stamped return envelopes is the best way for the JNHS to
33 maintain the cohort with a better cost-performance.
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42 **Other factors affecting the response**

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44 In addition to the effect of the type of return envelope and timing of the newsletter, the present
45 analysis showed interesting points with regard to factors predicting the response to the survey.
46 Participation in a previous survey increased the odds of responding to this survey. In particular,
47 participants who were involved in the most recent survey were 18 times more likely to return the
48 questionnaire (table 2). In addition, there appeared to be some differences in women's responses to the
49 survey based on their residence regions. As shown in table 2, women living in Hokkaido were more likely
50 than those living in Kanto to respond to the survey. In contrast, women living in Kyusyu and Okinawa
51 were less likely to respond to the survey
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56 Women who experienced menopause were more likely to participate in the present survey, even
57 after the odds was adjusted by age. The questionnaire of the JNHS included several items with respect to
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3 reproductive health-related issues, such as pregnancy and menopause. Recognizing the association of the
4 research issues with women's personal experiences would promote their involvement in the study. In
5 contrast, smokers in the previous survey were less likely to respond to the present questionnaire. Given a
6 recent negative image of smoking and the public trends against smoking, smokers would be reluctant to
7 answer questions with regard to their health. However, if this tendency becomes prominent, health effects
8 of smoking could be underestimated, especially in later surveys.

13 **Limitations**

14 There are several limitations to the present study. A major one refers to generalization of results.
15 The cohort of the JNHS follow-up survey consists of female healthcare professionals with a nursing
16 license who agreed to participate in the survey by signing an informed consent form. It may be
17 problematic to apply the results of the present analysis to a broader population. There is, however, a major
18 advantage of the present analysis. The JNHS is a nationwide occupational cohort study in Japan, and
19 drawing on data from the cohort study, we could randomly allocate items of research interest, that is, type
20 of return envelopes and timing of newsletter delivery, within the survey population.

26 **Disclosure of Conflict of Interest** The authors report no conflicts of interest.

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34 which is fully sponsored by the Japanese Ministry of Health, Labor, and Welfare.

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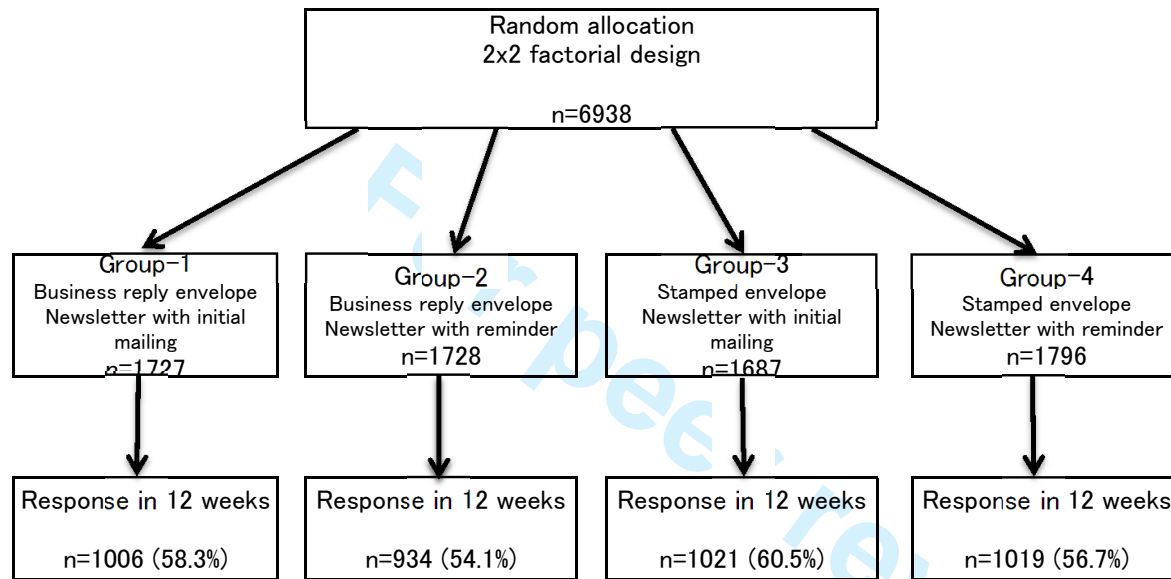


Figure 1 Diagram of cumulative response proportion by allocation group

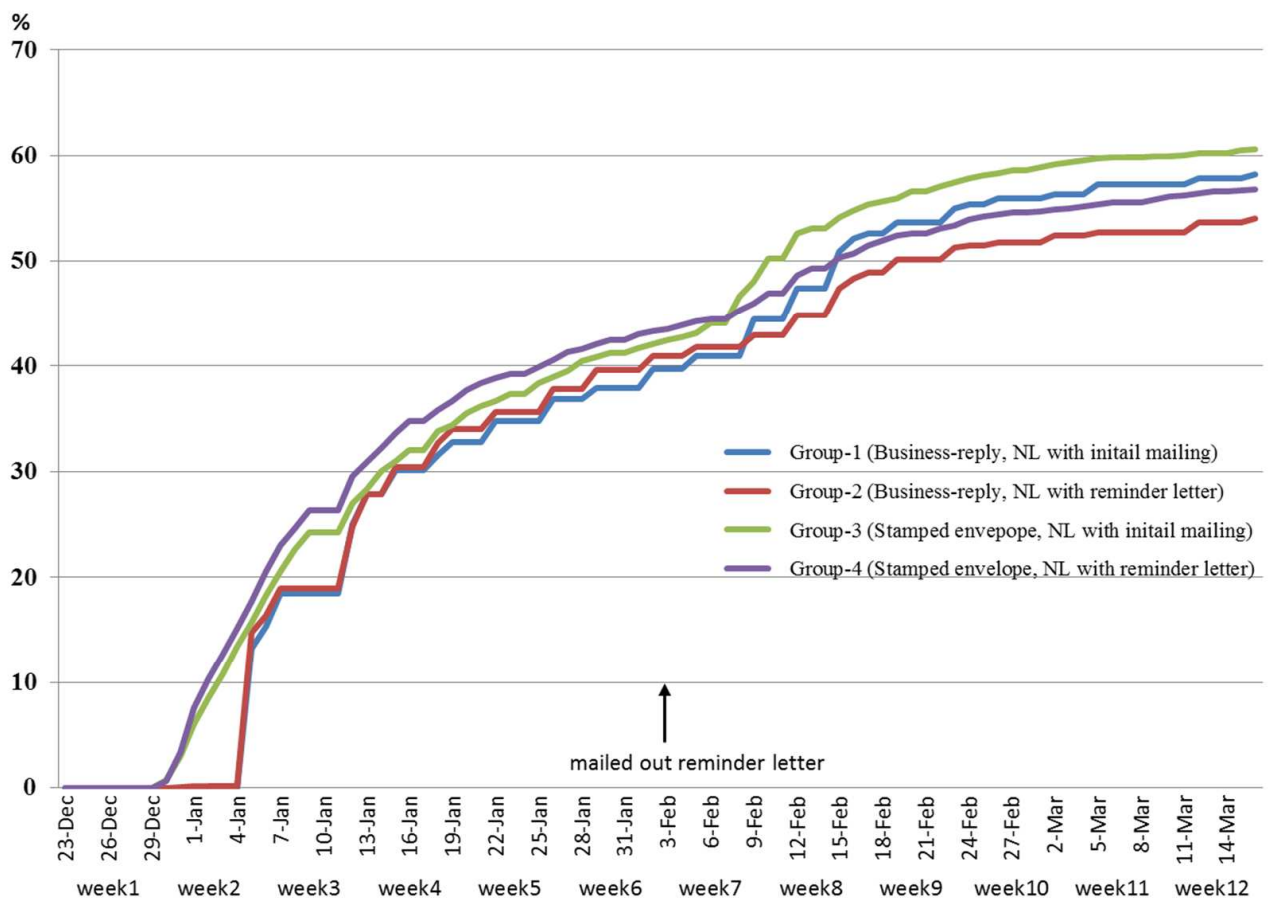


Figure 2 Cumulative response by randomly allocated group

Table 1. Demographic characteristics of the participants

| Type of return envelop Timing of newsletter delivery | Group-1 business reply with initial mailing n=1,727 | Group-2 business reply with reminder n=1,728 | Group-3 stamped with initial mailin; n=1,687 | Group-4 stamped with reminder n=1,796 | p-value |
|---|--|---|---|--|---------|
| Age at survey (years) | | | | | |
| Mean ± SD | 49.7±7.5 | 49.7±7.5 | 50.0±7.6 | 50.2±7.7 | 0.08 |
| Nursing license | | | | | |
| Registered nurse | 1412 (81.8%) | 1446 (83.7%) | 1390 (82.4%) | 1487 (82.8%) | 0.76 |
| Licensed nurse | 118 (6.8%) | 111 (6.4%) | 114 (6.8%) | 127 (7.1%) | |
| Midwives | 162 (9.4%) | 136 (7.9%) | 152 (9.0%) | 151 (8.4%) | |
| Public health nurse | 25 (1.4%) | 27 (1.6%) | 17 (1.0%) | 22 (1.2%) | |
| Unknown | 10 (0.6%) | 8 (0.5%) | 14 (0.8%) | 9 (0.5%) | |
| Work | | | | | |
| Working | 1599 (92.6%) | 1600 (92.6%) | 1565 (92.8%) | 1644 (91.5%) | 0.83 |
| Not working | 108 (6.3%) | 110 (6.4%) | 102 (6.0%) | 131 (7.3%) | |
| Unknown | 20 (1.2%) | 18 (1.0%) | 20 (1.2%) | 21 (1.2%) | |
| Region of residence | | | | | |
| Hokkaido | 22 (1.3%) | 31 (1.8%) | 28 (1.7%) | 28 (1.6%) | 0.80 |
| Tohoku | 192 (11.1%) | 188 (10.9%) | 183 (10.8%) | 207 (11.5%) | |
| Kanto | 284 (16.4%) | 272 (15.7%) | 260 (15.4%) | 264 (14.7%) | |
| Hokuriku_Koshin | 267 (15.5%) | 243 (14.1%) | 260 (15.4%) | 255 (14.2%) | |
| Tokai | 139 (8.0%) | 165 (9.5%) | 143 (8.5%) | 163 (9.1%) | |
| Kinki | 269 (15.6%) | 245 (14.2%) | 272 (16.1%) | 248 (13.8%) | |
| Cyugoku | 140 (8.1%) | 157 (9.1%) | 142 (8.4%) | 161 (9.0%) | |
| Shikoku | 136 (7.9%) | 125 (7.2%) | 132 (7.8%) | 154 (8.6%) | |
| Kjusyu | 250 (14.5%) | 280 (16.2%) | 240 (14.2%) | 285 (15.9%) | |
| Okinawa | 28 (1.6%) | 22 (1.3%) | 27 (1.6%) | 31 (1.7%) | |
| Type of residence area ¹⁾ | | | | | |
| Urban | 308 (17.8%) | 321 (18.6%) | 323 (19.1%) | 342 (19.0%) | 0.75 |
| Non-urban | 1419 (82.2%) | 1407 (81.4%) | 1364 (80.9%) | 1454 (81.0%) | |
| Smoking ²⁾ | | | | | |
| Smoker | 187 (10.8%) | 184 (10.6%) | 194 (11.5%) | 195 (10.9%) | 0.56 |
| Non smoker | 1537 (89.0%) | 1541 (89.2%) | 1485 (88.0%) | 1597 (88.9%) | |
| Unkown | 3 (0.2%) | 3 (0.2%) | 8 (0.5%) | 4 (0.2%) | |
| Drinking ²⁾ | | | | | |
| < 3 days a week | 1286 (74.5%) | 1275 (73.8%) | 1261 (74.7%) | 1359 (75.7%) | 0.70 |
| ≥ 3 days a week | 402 (23.3%) | 402 (23.3%) | 387 (22.9%) | 398 (22.2%) | |
| Unknown | 39 (2.3%) | 51 (3.0%) | 39 (2.3%) | 39 (2.2%) | |
| Pregnancy ²⁾ | | | | | |
| Pregnant | 13 (0.8%) | 15 (0.9%) | 21 (1.2%) | 21 (1.2%) | 0.15 |
| Not pregnant | 1702 (98.6%) | 1709 (98.9%) | 1651 (97.9%) | 1763 (98.2%) | |
| Unkown | 12 (0.7%) | 4 (0.2%) | 15 (0.9%) | 12 (0.7%) | |
| Menopause ²⁾ | | | | | |
| Postmenopausal | 603 (34.9%) | 617 (35.7%) | 625 (37.0%) | 690 (38.4%) | 0.07 |
| Premenopausal | 1103 (63.9%) | 1099 (63.6%) | 1046 (62.0%) | 1079 (60.1%) | |
| Unkown | 21 (1.2%) | 12 (0.7%) | 16 (0.9%) | 27 (1.5%) | |
| Participation in previous survey | | | | | |
| Wave II | 1506 (87.2%) | 1509 (87.3%) | 1490 (88.3%) | 1592 (88.6%) | 0.47 |
| Wave III | 1425 (82.5%) | 1429 (82.7%) | 1378 (81.7%) | 1485 (82.7%) | 0.85 |
| Wave IV | 1357 (78.6%) | 1366 (79.1%) | 1364 (80.9%) | 1431 (79.7%) | 0.38 |

1): urban areas are Tokyo metropolitan area and other 19 large cities designated by government ordinance

2): data in latest available survey

Table 2. Odds ratios for cumulative response of questionnaires in 12 weeks

| | Unadjusted | | Age-adjusted | |
|--|------------|-----------------|--------------|-----------------|
| | odds ratio | 95% CI | odds ratio | 95% C.I. |
| Interventions | | | | |
| Type of return envelope | | referent | | referent |
| Business-reply return envelope | 1.10 | (1.00 - 1.21) | 1.09 | (0.995 - 1.20) |
| Stamped return envelope | | | | |
| Timing of newsletter delivery | | referent | | referent |
| With reminder mailing | | | | |
| With initial mailing | 1.18 | (1.07 - 1.29) | 1.18 | (1.07 - 1.30) |
| Demographic and lifestyle factors | | | | |
| Age at survey (for one year increase) | 1.02 | (1.01 - 1.03) | - | |
| Nursing license | | | | |
| Registered nurse | | referent | | referent |
| Licensed nurse | 0.879 | (0.728 - 1.06) | 0.780 | (0.643 - 0.946) |
| Midwives | 0.932 | (0.786 - 1.10) | 0.934 | (0.788 - 1.11) |
| Public health nurse | 1.65 | (1.06 - 2.59) | 1.67 | (1.06 - 2.62) |
| Work | | | | |
| Not working | | referent | | referent |
| Working | 0.802 | (0.658 - 0.976) | 0.886 | (0.725 - 1.08) |
| Region of residence | | | | |
| Hokkaido | 1.66 | (1.08 - 2.54) | 1.64 | (1.07 - 2.52) |
| Tohoku | 1.02 | (0.848 - 1.23) | 0.986 | (0.817 - 1.19) |
| Kanto | | referent | | referent |
| Hokuriku Koshin | 0.976 | (0.821 - 1.16) | 0.937 | (0.787 - 1.12) |
| Tokai | 1.03 | (0.842 - 1.26) | 0.988 | (0.807 - 1.21) |
| Kinki | 0.968 | (0.814 - 1.15) | 0.959 | (0.806 - 1.14) |
| Cyugoku | 0.967 | (0.790 - 1.18) | 0.925 | (0.755 - 1.13) |
| Shikoku | 0.977 | (0.794 - 1.20) | 0.956 | (0.775 - 1.18) |
| Kysyu | 0.856 | (0.721 - 1.02) | 0.828 | (0.697 - 0.983) |
| Okinawa | 0.620 | (0.417 - 0.923) | 0.593 | (0.398 - 0.883) |
| Type of residence area | | | | |
| Not urban | | referent | | referent |
| Urban | 1.14 | (1.01 - 1.29) | 1.17 | (1.03 - 1.32) |
| Smoking | | | | |
| Non-smoker | | referent | | referent |
| Smoker | 0.624 | (0.536 - 0.726) | 0.634 | (0.545 - 0.738) |
| Drinking | | | | |
| < 3 days a week | | referent | | referent |
| ≥ 3 days a week | 0.907 | (0.810 - 1.02) | 0.896 | (0.800 - 1.00) |
| Pregnancy | | | | |
| Not pregnant | | referent | | referent |
| Pregnant | 1.05 | (0.651 - 1.69) | 1.26 | (0.776 - 2.03) |
| Menopause | | | | |
| Not postmenopausal | | referent | | referent |
| Postmenopausal | 1.52 | (1.37 - 1.68) | 1.52 | (1.30 - 1.78) |
| Participation in previous survey | | | | |
| Wave II not participated | | referent | | referent |
| participated | 2.08 | (1.79 - 2.40) | 2.01 | (1.74 - 2.33) |
| Wave III not participated | | referent | | referent |
| participated | 7.08 | (6.11 - 8.22) | 7.00 | (6.03 - 8.12) |
| Wave IV not participated | | referent | | referent |
| participated | 17.7 | (14.9 - 21.1) | 17.5 | (14.7 - 20.9) |

Table 3. Costs of business-reply envelope returns and stamped envelope returns

| | Scenario-1 | | | | | | Scenario-2 | | | | | |
|---|-------------------------|--------|------------|-------------------------|--------|------------|-------------------------|--------|------------|-------------------------|--------|------------|
| | business-reply envelope | | | Stamped return envelope | | | business-reply envelope | | | Stamped return envelope | | |
| | response rate = 50% | | | response rate = 55% | | | response rate = 80% | | | response rate = 88% | | |
| | Unit cost | Number | Total cost | Unit cost | Number | Total cost | Unit cost | Number | Total cost | Unit cost | Number | Total cost |
| Cost of Mailing | | | | | | | | | | | | |
| Postal cost for mailing out survey packet | ¥120 | 10,000 | ¥1,200,000 | ¥120 | 10,000 | ¥1,200,000 | ¥120 | 10,000 | ¥1,200,000 | ¥120 | 10,000 | ¥1,200,000 |
| Stamp for return envelope | | | | ¥120 | 10,000 | ¥1,200,000 | | | | ¥120 | 10,000 | ¥1,200,000 |
| Cost for post-payment by the recipient | ¥135 | 5,000 | ¥675,000 | | | | ¥135 | 8,000 | ¥1,080,000 | | | |
| Total cost | | | ¥1,875,000 | | | ¥2,400,000 | | | ¥2,280,000 | | | ¥2,400,000 |
| Number of responses | | | 5,000 | | | 5,500 | | | 8,000 | | | 8,800 |
| Cost per response | | | ¥375 | | | ¥436 | | | ¥285 | | | ¥273 |



CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|----------------------------------|---------|---|---------------------|
| Title and abstract | | | |
| | 1a | Identification as a randomised trial in the title | 0 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 0 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 1 |
| | 2b | Specific objectives or hypotheses | 1 |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 2 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | 2 |
| Participants | 4a | Eligibility criteria for participants | 2 |
| | 4b | Settings and locations where the data were collected | 2 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 2 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 3 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | 3 |
| Sample size | 7a | How sample size was determined | 2 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 2 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 2 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 2 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 2 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those | |

| | | | |
|----|--------------------------|---|----------|
| 1 | | | |
| 2 | | assessing outcomes) and how | |
| 3 | | | |
| 4 | | 11b If relevant, description of the similarity of interventions | |
| 5 | Statistical methods | 12a Statistical methods used to compare groups for primary and secondary outcomes | 3 |
| 6 | | 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses | 3 |
| 7 | | | |
| 8 | Results | | |
| 9 | Participant flow (a | 13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and | 3 |
| 10 | diagram is strongly | were analysed for the primary outcome | |
| 11 | recommended) | 13b For each group, losses and exclusions after randomisation, together with reasons | 3 |
| 12 | Recruitment | 14a Dates defining the periods of recruitment and follow-up | 2 |
| 13 | | 14b Why the trial ended or was stopped | |
| 14 | | | |
| 15 | Baseline data | 15 A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| 16 | Numbers analysed | 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was | Figure 1 |
| 17 | | by original assigned groups | |
| 18 | | | |
| 19 | Outcomes and | 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its | 4 |
| 20 | estimation | precision (such as 95% confidence interval) | |
| 21 | | 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended | |
| 22 | Ancillary analyses | 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing | 4 |
| 23 | | pre-specified from exploratory | |
| 24 | | | |
| 25 | Harms | 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | |
| 26 | | | |
| 27 | Discussion | | |
| 28 | Limitations | 20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 6 |
| 29 | Generalisability | 21 Generalisability (external validity, applicability) of the trial findings | 6 |
| 30 | Interpretation | 22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 4-5 |
| 31 | | | |
| 32 | Other information | | |
| 33 | Registration | 23 Registration number and name of trial registry | |
| 34 | Protocol | 24 Where the full trial protocol can be accessed, if available | |
| 35 | Funding | 25 Sources of funding and other support (such as supply of drugs), role of funders | 6 |
| 36 | | | |

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38 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

39 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

40 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Effect of stamped reply envelopes and timing of newsletter delivery on response rates of mail survey: A randomised controlled trial in a prospective cohort study

Abstract

Objective To examine the effects of stamped reply envelope and the timing of newsletter distribution.

Design A randomized controlled trial in a prospective cohort study with a 2x2 factorial design of two interventions.

Setting The Japan Nurses' Health Study (JNHS), a prospective cohort study for women's health.

Participants The present study included 6,938 women who were part of the first-year entry cohort for the fifth wave of the biannual follow-up survey of the JNHS.

Intervention The participants were randomly allocated into four groups; Group-1 (business-reply, newsletter with initial mailing), Group-2 (business-reply, newsletter with reminder), Group-3 (stamped envelopes, newsletter with initial mailing), and Group-4 (stamped envelopes, newsletter with reminder). The thank-you and reminder letters were mailed out at the end of the sixth week. This study was censored at the end of 12 weeks.

Main outcome measures Main outcome measures were cumulative response at the end of six and twelve weeks after mailing out the questionnaire.

Results The cumulative response at twelve weeks were 58.3% for Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 ($p=0.001$). The odds of the response was higher for stamped envelopes than for business-reply envelopes (OR [95%CI]=1.10[1.00-1.21]). The odds was higher for newsletter delivery with initial mailing than for with reminder (1.18[1.07-1.29]). The response in first six weeks for stamped envelope was significantly higher than for business-reply envelope ($p=0.047$). Although the response in six weeks for women received the newsletter with initial mailing was lower than for women who did not, the proportions did not differ significantly ($p=0.291$).

Conclusions The style of return envelope affected response rates of mail-survey. The results of this study suggest that practices of provision of the additional information, should be handled individually in advance, as a separate event from sending follow-up questionnaire or reminder letters.

INTRODUCTION

The Japan Nurses' Health Study (JNHS) is a nationwide prospective occupational cohort study to explore women's health in Japan¹. The JNHS was designed as a prospective study, which consists of a cross-sectional baseline survey that includes a 6-year entry period from 2001 to 2007, and a 10-year follow-up study, from 2001 to 2017¹. For a prospective cohort study, maintaining the cohort, that is, maintaining high follow-up response rates is a major issue. A cohort study is used to estimate risks, rates, or occurrence times of events, and thus requires that the whole cohort remain under observation for the entire follow-up period². Loss of subjects during the study period lowers the validity of the study, because it makes estimation more difficult due to unknown outcomes of lost subjects. Prospective cohort studies that take many years are likely to experience difficulties with locating people over the study period². Follow-up studies that maintain less than about 60% of subjects are considered insufficient to provide confident estimates².

In an effort to achieve high response rates, offering incentives to respondents has become prevalent. A systematic review of 292 surveys showed that both monetary and non-monetary incentives improved the odds of returning the questionnaire³. Also, prior studies reported that the odds of receiving responses were increased when post-office stamped reply envelopes were used compared with enclosing pre-paid business reply envelopes³, although the results were mixed.⁴ Furthermore, sending advance letters has been shown to increase response rates, as well as providing follow-up contacts such reminder letters, telephone contacts, and providing nonrespondents with a second copy of the questionnaire^{3,5,6,7}. In addition, a study has reported that sending a cover letter that asks recipients to decline participation within 7 days if they do not want to participate, raises response rates⁸. Yet, using information leaflets upon recruitment did not affect the number of participants in the survey⁹.

As far as the JNHS is concerned, follow-up questionnaires are mailed to the cohort along with a newsletter. The newsletters are designed to update participants on new information about women's health and the progress of the JNHS. Women who do not respond to the first mailed questionnaire receive a second mailing within 6 months. Subsequently, women who still do not respond receive a third and fourth questionnaire. If the JNHS coordination center cannot contact participants by mail, the JNHS Follow-up Committee confirms if the subject has moved, and a questionnaire is sent to the new address, which is obtained from the resident registry of the corresponding local district.

In the present study, drawing on data from the fifth wave of the JNHS, we examined whether and how stamped reply envelopes compared to business reply envelopes and the timing of newsletter delivery affected the odds of a response. In Japan, studies that receive public funds are not allowed to offer incentives or stamped reply envelopes to survey participants as participants may not respond, and such a practice is regarded as a waste of research expenses for a study supported by the national government. However, for the JNHS it is expected that the use of stamped envelopes and delivery of a newsletter will have favorable effects on response rates. It is hoped that because the present study population draws from

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3 a homogeneous cohort consisting of healthcare professionals, information regarding women's health in
4 general and results of previous JNHS surveys would encourage participant involvement in the study.
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8 **METHODS**

9 **Objectives**

10 The primary objective of the study was to examine whether stamped reply envelopes and
11 enclosed newsletter improve response rates of mail survey by a 2x2 factorial randomised controlled trial in
12 the Japan Nurses' Health Study cohort. The secondary objective was to explore the demographic and
13 lifestyle factors that affect response rate of mail survey in a women cohort.
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17 **Participants**

18 The JNHS consists of a cross-sectional baseline survey that includes a 6-year entry period, from
19 2001 to 2007 and a 10-year follow-up study, from 2001 to 2017. The study population was designed for
20 female registered nurse, licensed practical nurses, public health nurses, and/or midwives, who were at
21 least 30 years of age and resident in Japan. Although the participants were licensed to practice nursing,
22 they did not necessarily function as nurses. The baseline survey includes 49,927 responses from
23 participants in Japan. Among them, 14,844 women signed an informed consent form and participated in
24 the follow-up survey. Institutional review boards of Gunma University and the National Institute of Public
25 Health reviewed and approved the JNHS study protocol. The study design of the JNHS has been presented
26 elsewhere¹. The present study included 6,938 women who were in the first-year entry cohort for the
27 fifth-wave follow-up survey of the JNHS.
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34 **Intervention**

35 To estimate the effect of types of return envelope and timing of newsletters, women were
36 randomly allocated into the four groups with a 2x2 factorial design. For Groups 1 and 2, business-reply
37 return envelopes for post-payment by the recipient were enclosed, and for Groups 3 and 4, stamped return
38 envelopes were provided. In terms of timing of newsletter delivery, for Groups 1 and 3, the newsletter was
39 enclosed when the questionnaires were mailed out; for Groups 2 and 4, the newsletters were sent with the
40 reminder letters. The questionnaires were mailed to participants on December 22, 2009, and a thank-you
41 and reminder letter was mailed out to all respondents, (regardless of whether they had already returned
42 their self-administered questionnaires to the data center) at the end of the sixth week (February 2, 2010).
43 The present study was censored at May 16, 2010 (12 weeks or 84 days). We did not perform any power
44 calculations based on primary hypothesis of this study.
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51 When the participants registered at baseline survey, the sequential unique 7-digit ID numbers
52 were assigned randomly. According to the ID numbers, participants were allocated to the four groups. The
53 allocated group number for each participant was the remainder when the ID number was divided by four.
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56 **Measurements**

57 Primary outcome measure was cumulative response proportion at 12 weeks after
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mailing out the questionnaire. Secondary outcome measure was cumulative response at the end of 6 weeks after initial mailing, just before delivering the reminder letters.

The participants were simultaneously randomised to two interventions: type of return envelope (business reply vs. stamped return envelopes) and timing of newsletter delivery (newsletter with initial mailing vs newsletter with reminder). Besides these two variables, following demographic and lifestyle variables were used to explore the factors affecting response rates: age at the survey, type of nursing license (registered nurse, licensed nurse, midwives, and public health nurse), region of residence (Hokkaido, Tohoku, Kanto, Hokuriku_Koshin, Tokai, Kinki, Cyugoku, Shikoku, Kyusyu, and Okinawa), and type of residence area (urban [Tokyo metropolitan area and other 19 large cities designated by government ordinance] and not-urban area), work status (not-working and working), smoking status (smoking and not-smoking), alcohol drinking (< 3 days a week and \geq 3 days a week), pregnancy (pregnant and not-pregnant), menopausal status (postmenopausal and others). All the data were obtained from the available latest wave of survey. These variables included factors previously studied^{10, 11, 12} and reproductive health related issues in women.

Statistical Analysis

Characteristics of participants were compared between groups using ANOVA and chi-square test to check the relevance of randomization process. Before examining main effect of two interventions, type of return envelope (business reply vs stamped) and timing of newsletter provision (with initial mailing vs. with reminder) on cumulative response proportion at 6 and 12 weeks after initial mailing, the interaction of these two interventions was tested by logistic regression model. The main effects of the interventions were tested by chi-square test. In order to examine the factors affecting the responses in 12 weeks after initial mailing, logistic regression models were used to estimate unadjusted and age-adjusted odds ratios (ORs) and their 95% confidence intervals (CIs). For all statistical analysis, SAS Ver. 9.1 (SAS Institute, North Carolina, USA) was used and $p < 0.05$ was set as statistically significant.

RESULTS

Characteristics of Participants

Of the 6938 women of the first-year entry JNHS cohort, 1727, 1728, 1687, and 1796 women were randomised into Group-1, Group-2, Group-3, and Group-4, respectively (figure 1). With the questionnaire, 3455 received business-reply return envelopes and 3483 women were provided with stamped envelopes. A total of 3414 women received the newsletter with initial mailing and 3524 women received the newsletter with thank-you and reminder mailing. The four groups did not differ significantly in demographic and lifestyle characteristics (table 1). Although there were slight differences among four groups in age at the survey ($p=0.081$) and menopausal status ($p=0.066$), no significant differences were found between any pairs of groups.

Cumulative response proportion by group

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4 The cumulative response proportions at 12 weeks were 58.3% for women in Group-1, 54.1%
5 for Group-2, 60.5% for Group-3, and 56.7% for Group-4 (figure 1), and these proportions significantly
6 differed among the groups ($\chi^2=15.5$; d.f.=3; $p=0.001$). There was not statistically significant interaction
7 effect of two interventions, type of enclosed return envelope and timing of newsletter delivery, on the
8 proportions ($p=0.881$). The response for women who received stamped reply envelopes (Groups-3 and 4)
9 was 58.6%, and it was significantly higher compared with the proportion of 56.2% for those who received
10 business-reply envelopes (Groups-1 and 2) ($\chi^2=4.15$; d.f.=1; $p=0.042$). With respect to the effect of
11 newsletter, the cumulative response proportion at 12 week when the newsletter was delivered at initial
12 mailing was significantly higher than the response when the newsletter was delivered with thank-you and
13 reminder letters ($\chi^2=11.1$; d.f.=1; $p<0.001$); 59.4% for Group-1 and 3 and 55.4% for Group-2 and 4.

14
15 We compared the cumulative proportions at 6 weeks to confirm the main effects of interventions
16 without the effect of reminder mailing (figure 2). The proportion at 6 weeks for business-reply envelopes
17 (Groups-1 and 2) was 40.3% and the proportion for stamped reply envelopes (Groups-3 and 4) was 42.7%,
18 and those proportions differed significantly ($\chi^2=3.93$; d.f.=1; $p=0.047$). The proportion for women
19 received the newsletter with initial mailing (Group-1 and 3) was 40.9% and the proportion for women who
20 did not receive it with initial mailing (Group-2 and 4) was 42.1%, and these proportions did not differ
21 significantly ($\chi^2=1.11$; d.f.=1; $p=0.291$).

22 Factors affecting response

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24 The ORs and 95% CIs for cumulative responses at 12 weeks are shown in Table 1. With respect
25 to two interventions, unadjusted ORs showed statistically significant effects. The stamped envelopes
26 raised the response by 10% relative to provision of business-reply envelopes (OR [95%CI] = 1.10 [1.00 -
27 1.21]), and the newsletter delivery with initial mailing raised the response by 18% relative to the delivery
28 with reminder letters (1.18 [1.07 - 1.29]). However, when adjusted by age at the survey, the effect of
29 stamped return envelopes became not significant (table 2).

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31 Regarding other factors that showed significant effects on the response by age-adjusted
32 analyses, nursing license, region of residence, type of residence area, smoking, menopause, and
33 participation in previous survey were associated with the odds of response.

34 DISCUSSION

35 Timing of newsletter delivery and type of return envelope

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37 Results of the present study showed that provision of the newsletters with the questionnaires
38 tended to decrease the odds of returning the self-administered questionnaire. In addition, if the newsletters
39 were provided to participants 6 weeks later with reminder letters, it would further keep participants
40 (non-responders at that point) from returning their questionnaires. Thus, the results suggest that each
41 practice, such as provision of information, request for collaboration, and encouragement of contribution,
42 should be managed individually, as separate events in advance. As prior studies^{3, 10, 14} documented that
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3 advanced contacts via letters, cards, and phone calls increase the rates, if the update of the survey is
4 offered via newsletter to respondents in advance, it may facilitate their understanding of the research
5 issues and then improve response rates as well as enhance the quality of responses by reducing the number
6 of items left blank or incomplete and decreasing inconsistent answers.
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10 In the light of cost-performance, some studies suggest that allocating large sums of money to
11 achieve high response rates may not always significantly improve the quality of the sample^{13, 14, 15}. Prior
12 studies documented that with properly high response rates (approximately 70%), the bias due to
13 non-response was unlikely to affect estimation of the survey^{13, 14, 15}. However, for a follow-up cohort
14 survey like the JNHS, maintaining high follow-up response rates is crucial to maintaining the cohort.
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17 Provision of a stamped return envelope had a significant effect of raising the odds of returning
18 the questionnaire in the JNHS follow-up survey. Although there is an argument that providing stamped
19 return envelopes is an inappropriate use of research expenses (especially for research with public funds)
20 and is not cost-beneficial, it depends on the survey response rates that you expect to achieve. We should
21 discuss about the cost-performance based on the results of an actual cost analysis¹⁶. If we assume
22 provision of stamped return envelopes, compared to business-reply envelopes for post-payment by the
23 recipient, increases the response rate by 10%, in a case survey of 10,000 participants, when the response
24 rate with business-reply envelope is 50%, assuming that the stamped return envelope approach can
25 improve the odds of response by 10%, the business-reply approach is better in terms of cost-performance
26 (table 3). However, if the response rate is 80% in a survey of 10,000 participants, mailing costs for the
27 stamped return envelope approach and for business reply envelope approach will be 285 yen/response and
28 273 yen/response, respectively. Consequently, if the response rate is as high as 80%, the stamped return
29 envelope approach will be more advantageous than the business-reply envelope approach in terms of
30 cost-performance. In that case, providing stamped return envelopes is the best way for the JNHS to
31 maintain the cohort with a better cost-performance.
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34 **Other factors affecting the response**

35 In addition to the effect of the type of return envelope and timing of the newsletter, the present
36 analysis showed interesting points with regard to factors predicting the response to the survey.
37 Participation in a previous survey increased the odds of responding to this survey. In particular,
38 participants who were involved in the most recent survey were 18 times more likely to return the
39 questionnaire (table 2). In addition, there appeared to be some differences in women's responses to the
40 survey based on their residence regions. As shown in table 2, women living in Hokkaido were more likely
41 than those living in Kanto to respond to the survey. In contrast, women living in Kyusyu and Okinawa
42 were less likely to respond to the survey
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45 Women who experienced menopause were more likely to participate in the present survey, even
46 after the odds was adjusted by age. The questionnaire of the JNHS included several items with respect to
47 reproductive health-related issuers, such as pregnancy and menopause. Recognizing the association of the
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3 research issues with women's personal experiences would promote their involvement in the study. In
4 contrast, smokers in the previous survey were less likely to respond to the present questionnaire. Given a
5 recent negative image of smoking and the public trends against smoking, smokers would be reluctant to
6 answer questions with regard to their health. However, if this tendency becomes prominent, health effects
7 of smoking could be underestimated, especially in later surveys.
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10 11 **Limitations**

12 There are several limitations to the present study. A major one refers to generalization of results.
13 The cohort of the JNHS follow-up survey consists of female healthcare professionals with a nursing
14 license who agreed to participate in the survey by signing an informed consent form. It may be
15 problematic to apply the results of the present analysis to a broader population. There is, however, a major
16 advantage of the present analysis. The JNHS is a nationwide occupational cohort study in Japan, and
17 drawing on data from the cohort study, we could randomly allocate items of research interest, that is, type
18 of return envelopes and timing of newsletter delivery, within the survey population.
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25 **Disclosure of Conflict of Interest** The authors report no conflicts of interest.

26 **Acknowledgements** We are grateful to the Japanese Nursing Association (47 prefectures' individual
27 Nursing Associations), and Japan Society of Menopause and Women's Health for their collaboration in
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29 Monitoring Committee, which periodically monitors the study process. The JNHS is supported partly by a
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31 Science. The present study is funded by the National Center for Child Health and Development (NCCHD),
32 which is fully sponsored by the Japanese Ministry of Health, Labor, and Welfare.
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Effect of stamped reply envelopes and timing of newsletter delivery on response rates of mail survey: A randomised controlled trial in a prospective cohort study

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Effect of stamped reply envelopes and timing of newsletter delivery on response rates of mail survey: A randomised controlled trial in a prospective cohort study

Abstract

Objective To examine the effects of stamped reply envelope and the timing of newsletter distribution.

Design A randomized controlled trial in a prospective cohort study with a 2x2 factorial design of two interventions.

Setting The Japan Nurses' Health Study (JNHS), a prospective cohort study for women's health.

Participants The present study included 6,938 women who were part of the first-year entry cohort for the fifth wave of the biannual follow-up survey of the JNHS.

Intervention The participants were randomly allocated into four groups; Group-1 (business-reply, newsletter with initial mailing), Group-2 (business-reply, newsletter with reminder), Group-3 (stamped envelopes, newsletter with initial mailing), and Group-4 (stamped envelopes, newsletter with reminder). The thank-you and reminder letters were mailed out at the end of the sixth week. This study was censored at the end of 12 weeks.

Main outcome measures Main outcome measures were cumulative response at the end of six and twelve weeks after mailing out the questionnaire.

Results The cumulative response at twelve weeks were 58.3% for Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 ($p=0.001$). The odds of the response was higher for stamped envelopes than for business-reply envelopes (OR [95%CI]=1.10[1.00-1.21]). The odds was higher for newsletter delivery with initial mailing than for with reminder (1.18[1.07-1.29]). The response in first six weeks for stamped envelope was significantly higher than for business-reply envelope ($p=0.047$). Although the response in six weeks for women received the newsletter with initial mailing was lower than for women who did not, the proportions did not differ significantly ($p=0.291$).

Conclusions The style of return envelope affected response rates of mail-survey. The results of this study suggest that practices of provision of the additional information, should be handled individually in advance, as a separate event from sending follow-up questionnaire or reminder letters.

INTRODUCTION

The Japan Nurses' Health Study (JNHS) is a nationwide prospective occupational cohort study to explore women's health in Japan¹. The JNHS was designed as a prospective study, which consists of a cross-sectional baseline survey that includes a 6-year entry period from 2001 to 2007, and a 10-year follow-up study, from 2001 to 2017¹. For a prospective cohort study, maintaining the cohort, that is, maintaining high follow-up response rates is a major issue. A cohort study is used to estimate risks, rates, or occurrence times of events, and thus requires that the whole cohort remain under observation for the entire follow-up period². Loss of subjects during the study period lowers the validity of the study, because it makes estimation more difficult due to unknown outcomes of lost subjects. Prospective cohort studies that take many years are likely to experience difficulties with locating people over the study period². Follow-up studies that maintain less than about 60% of subjects are considered insufficient to provide confident estimates².

In an effort to achieve high response rates, offering incentives to respondents has become prevalent. A systematic review of 292 surveys showed that both monetary and non-monetary incentives improved the odds of returning the questionnaire³. Also, prior studies reported that the odds of receiving responses were increased when post-office stamped reply envelopes were used compared with enclosing pre-paid business reply envelopes³, although the results were mixed.⁴ Furthermore, sending advance letters has been shown to increase response rates, as well as providing follow-up contacts such reminder letters, telephone contacts, and providing nonrespondents with a second copy of the questionnaire^{3,5,6,7}. In addition, a study has reported that sending a cover letter that asks recipients to decline participation within 7 days if they do not want to participate, raises response rates⁸. Yet, using information leaflets upon recruitment did not affect the number of participants in the survey⁹.

As far as the JNHS is concerned, follow-up questionnaires are mailed to the cohort along with a newsletter. The newsletters are designed to update participants on new information about women's health and the progress of the JNHS. Women who do not respond to the first mailed questionnaire receive a second mailing within 6 months. Subsequently, women who still do not respond receive a third and fourth questionnaire. If the JNHS coordination center cannot contact participants by mail, the JNHS Follow-up Committee confirms if the subject has moved, and a questionnaire is sent to the new address, which is obtained from the resident registry of the corresponding local district.

In the present study, drawing on data from the fifth wave of the JNHS, we examined whether and how stamped reply envelopes compared to business reply envelopes and the timing of newsletter delivery affected the odds of a response. In Japan, studies that receive public funds are not allowed to offer incentives or stamped reply envelopes to survey participants as participants may not respond, and such a practice is regarded as a waste of research expenses for a study supported by the national government. However, for the JNHS it is expected that the use of stamped envelopes and delivery of a newsletter will have favorable effects on response rates. It is hoped that because the present study population draws from

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3 a homogeneous cohort consisting of healthcare professionals, information regarding women's health in
4 general and results of previous JNHS surveys would encourage participant involvement in the study.
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8 **METHODS**

9 **Objectives**

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11 The primary objective of the study was to examine whether stamped reply envelopes and
12 enclosed newsletter improve response rates of mail survey by a 2x2 factorial randomised controlled trial in
13 the Japan Nurses' Health Study cohort. The secondary objective was to explore the demographic and
14 lifestyle factors that affect response rate of mail survey in a women cohort.
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17 **Participants**

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19 The JNHS consists of a cross-sectional baseline survey that includes a 6-year entry period, from
20 2001 to 2007 and a 10-year follow-up study, from 2001 to 2017. The study population was designed for
21 female registered nurse, licensed practical nurses, public health nurses, and/or midwives, who were at
22 least 30 years of age and resident in Japan. Although the participants were licensed to practice nursing,
23 they did not necessarily function as nurses. The baseline survey includes 49,927 responses from
24 participants in Japan. Among them, 14,844 women signed an informed consent form and participated in
25 the follow-up survey. Institutional review boards of Gunma University and the National Institute of Public
26 Health reviewed and approved the JNHS study protocol. The study design of the JNHS has been presented
27 elsewhere¹. The present study included 6,938 women who were in the first-year entry cohort for the
28 fifth-wave follow-up survey of the JNHS.
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34 **Intervention**

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36 To estimate the effect of types of return envelope and timing of newsletters, women were
37 randomly allocated into the four groups with a 2x2 factorial design. For Groups 1 and 2, business-reply
38 return envelopes for post-payment by the recipient were enclosed, and for Groups 3 and 4, stamped return
39 envelopes were provided. In terms of timing of newsletter delivery, for Groups 1 and 3, the newsletter was
40 enclosed when the questionnaires were mailed out; for Groups 2 and 4, the newsletters were sent with the
41 reminder letters. The questionnaires were mailed to participants on December 22, 2009, and a thank-you
42 and reminder letter was mailed out to all respondents, (regardless of whether they had already returned
43 their self-administered questionnaires to the data center) at the end of the sixth week (February 2, 2010).
44 The present study was censored at May 16, 2010 (12 weeks or 84 days). Sample size was determined by
45 the size of the available cohort. With an expected number of 3469 (i.e. 6938/2) per group, and a reference
46 response rate of 60%, for 80% power and 5% significance, the detectable difference in response rate was
47 $\pm 3.3\%$.
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54 When the participants registered at baseline survey, the sequential unique 7-digit ID numbers
55 were assigned randomly by the JNHS data center. According to the ID numbers, participants were
56 allocated to the four groups. The allocated group number for each participant was the remainder when the
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3 ID number was divided by four.
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5 **Measurements**

6 Primary outcome measure was cumulative response proportion at 12 weeks after
7 mailing out the questionnaire. Secondary outcome measure was cumulative response at the end
8 of 6 weeks after initial mailing, just before delivering the reminder letters.
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10 The participants were simultaneously randomised to two interventions: type of return
11 envelope (business reply vs. stamped return envelopes) and timing of newsletter delivery
12 (newsletter with initial mailing vs newsletter with reminder). Besides these two variables, following
13 demographic and lifestyle variables were used to explore the factors affecting response rates: age at the
14 survey, type of nursing license (registered nurse, licensed nurse, midwives, and public health nurse),
15 region of residence (Hokkaiko, Tohoku, Kanto, Hokuriku_Koshin, Tokai, Kinki, Cyugoku, Shikoku,
16 Kyusyu, and Okinawa), and type of residence area (urban [Tokyo metropolitan area and other 19 large
17 cities designated by government ordinance] and. not-urban area), work status (not-working and working),
18 smoking status (smoking and not- smoking), alcohol drinking (< 3 days a week and \geq 3 days a week),
19 pregnancy (pregnant and not-pregnant), menopausal status (postmenopausal and others). All the data were
20 obtained from the available latest wave of survey. These variables included factors previously studied ^{10, 11,}
21 ¹² and reproductive health related issues in women.
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30 **Statistical Analysis**

31 Characteristics of participants were compared between groups using ANOVA and chi-square test
32 to check the relevance of randomization process. Before examining main effect of two interventions, type
33 of return envelope (business reply vs stamped) and timing of newsletter provision (with initial mailing vs.
34 with reminder) on cumulative response proportion at 6 and 12 weeks after initial mailing, the interaction
35 of these two interventions was tested by logistic regression model. The main effects of the interventions
36 were tested by chi-square test. In order to examine the factors affecting the responses in 12 weeks after
37 initial mailing, logistic regression models were used to estimate unadjusted and age-adjusted odds ratios
38 (ORs) and their 95% confidence intervals (CIs). For all statistical analysis, SAS Ver. 9.1 (SAS Institute,
39 North Carolina, USA) was used and $p < 0.05$ was set as statistically significant.
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47 **RESULTS**

48 **Characteristics of Participants**

49 Of the 6938 women of the first-year entry JNHS cohort, 1727, 1728, 1687, and 1796 women
50 were randomised into Group-1, Group-2, Group-3, and Group-4, respectively (figure 1). With the
51 questionnaire, 3455 received business-reply return envelopes and 3483 women were provided with
52 stamped envelopes. A total of 3414 women received the newsletter with initial mailing and 3524 women
53 received the newsletter with thank-you and reminder mailing. The four groups did not differ significantly
54 in demographic and lifestyle characteristics (table 1).
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Cumulative response proportion by group

The cumulative response proportions at 12 weeks were 58.3% for women in Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 (figure 1), and these proportions significantly differed among the groups ($\chi^2=15.5$; d.f.=3; $p=0.001$). There was not statistically significant interaction effect of two interventions, type of enclosed return envelope and timing of newsletter delivery, on the proportions ($p=0.881$). The response for women who received stamped reply envelopes (Groups-3 and 4) was 58.6%, and it was significantly higher compared with the proportion of 56.2% for those who received business-reply envelopes (Groups-1 and 2) ($\chi^2=4.15$; d.f.=1; $p=0.042$). With respect to the effect of newsletter, the cumulative response proportion at 12 week when the newsletter was delivered at initial mailing was significantly higher than the response when the newsletter was delivered with thank-you and reminder letters ($\chi^2=11.1$; d.f.=1; $p<0.001$); 59.4% for Group-1 and 3 and 55.4% for Group-2 and 4.

We compared the cumulative proportions at 6 weeks to confirm the main effects of interventions without the effect of reminder mailing (figure 2). The proportion at 6 weeks for business-reply envelopes (Groups-1 and 2) was 40.3% and the proportion for stamped reply envelopes (Groups-3 and 4) was 42.7%, and those proportions differed significantly ($\chi^2=3.93$; d.f.=1; $p=0.047$). The proportion for women received the newsletter with initial mailing (Group-1 and 3) was 40.9% and the proportion for women who did not receive it with initial mailing (Group-2 and 4) was 42.1%, and these proportions did not differ significantly ($\chi^2=1.11$; d.f.=1; $p=0.291$).

Factors affecting response

The ORs and 95% CIs for cumulative responses at 12 weeks are shown in Table 1. With respect to two interventions, unadjusted ORs showed statistically significant effects. The stamped envelopes raised the response by 10% relative to provision of business-reply envelopes (OR [95%CI] = 1.10 [1.00 - 1.21]), and the newsletter delivery with initial mailing raised the response by 18% relative to the delivery with reminder letters (1.18 [1.07 - 1.29]). However, when adjusted by age at the survey, the effect of stamped return envelopes became not significant (table 2).

Regarding other factors that showed significant effects on the response by age-adjusted analyses, nursing license, region of residence, type of residence area, smoking, menopause, and participation in previous survey were associated with the odds of response.

DISCUSSION

Timing of newsletter delivery and type of return envelope

Results of the present study showed that provision of the newsletters with the questionnaires tended to decrease the odds of returning the self-administered questionnaire. In addition, if the newsletters were provided to participants 6 weeks later with reminder letters, it would further keep participants (non-responders at that point) from returning their questionnaires. Thus, the results suggest that each practice, such as provision of information, request for collaboration, and encouragement of contribution,

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3 should be managed individually, as separate events in advance. As prior studies^{3, 10, 14} documented that
4 advanced contacts via letters, cards, and phone calls increase the rates, if the update of the survey is
5 offered via newsletter to respondents in advance, it may facilitate their understanding of the research
6 issues and then improve response rates as well as enhance the quality of responses by reducing the number
7 of items left blank or incomplete and decreasing inconsistent answers.
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11 In the light of cost-performance, some studies suggest that allocating large sums of money to
12 achieve high response rates may not always significantly improve the quality of the sample^{13, 14, 15}. Prior
13 studies documented that with properly high response rates (approximately 70%), the bias due to
14 non-response was unlikely to affect estimation of the survey^{13, 14, 15}. However, for a follow-up cohort
15 survey like the JNHS, maintaining high follow-up response rates is crucial to maintaining the cohort.
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19 Provision of a stamped return envelope had a significant effect of raising the odds of returning
20 the questionnaire in the JNHS follow-up survey. Although there is an argument that providing stamped
21 return envelopes is an inappropriate use of research expenses (especially for research with public funds)
22 and is not cost-beneficial, it depends on the survey response rates that you expect to achieve. We should
23 discuss about the cost-performance based on the results of an actual cost analysis¹⁶. If we assume
24 provision of stamped return envelopes, compared to business-reply envelopes for post-payment by the
25 recipient, increases the response rate by 10%, in a case survey of 10,000 participants, when the response
26 rate with business-reply envelope is 50%, assuming that the stamped return envelope approach can
27 improve the odds of response by 10%, the business-reply approach is better in terms of cost-performance
28 (table 3). However, if the response rate is 80% in a survey of 10,000 participants, mailing costs for the
29 stamped return envelope approach and for business reply envelope approach will be 285 yen/response and
30 273 yen/response, respectively. Consequently, if the response rate is as high as 80%, the stamped return
31 envelope approach will be more advantageous than the business-reply envelope approach in terms of
32 cost-performance. In that case, providing stamped return envelopes is the best way for the JNHS to
33 maintain the cohort with a better cost-performance.
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42 **Other factors affecting the response**

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44 In addition to the effect of the type of return envelope and timing of the newsletter, the present
45 analysis showed interesting points with regard to factors predicting the response to the survey.
46 Participation in a previous survey increased the odds of responding to this survey. In particular,
47 participants who were involved in the most recent survey were 18 times more likely to return the
48 questionnaire (table 2). In addition, there appeared to be some differences in women's responses to the
49 survey based on their residence regions. As shown in table 2, women living in Hokkaido were more likely
50 than those living in Kanto to respond to the survey. In contrast, women living in Kyusyu and Okinawa
51 were less likely to respond to the survey
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56 Women who experienced menopause were more likely to participate in the present survey, even
57 after the odds was adjusted by age. The questionnaire of the JNHS included several items with respect to
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3 reproductive health-related issuers, such as pregnancy and menopause. Recognizing the association of the
4 research issues with women's personal experiences would promote their involvement in the study. In
5 contrast, smokers in the previous survey were less likely to respond to the present questionnaire. Given a
6 recent negative image of smoking and the public trends against smoking, smokers would be reluctant to
7 answer questions with regard to their health. However, if this tendency becomes prominent, health effects
8 of smoking could be underestimated, especially in later surveys.

13 **Limitations**

14 There are several limitations to the present study. A major one refers to generalization of results.
15 The cohort of the JNHS follow-up survey consists of female healthcare professionals with a nursing
16 license who agreed to participate in the survey by signing an informed consent form. It may be
17 problematic to apply the results of the present analysis to a broader population. There is, however, a major
18 advantage of the present analysis. The JNHS is a nationwide occupational cohort study in Japan, and
19 drawing on data from the cohort study, we could randomly allocate items of research interest, that is, type
20 of return envelopes and timing of newsletter delivery, within the survey population.

26 **Disclosure of Conflict of Interest** The authors report no conflicts of interest.

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31 Monitoring Committee, which periodically monitors the study process. The JNHS is supported partly by a
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34 which is fully sponsored by the Japanese Ministry of Health, Labor, and Welfare.

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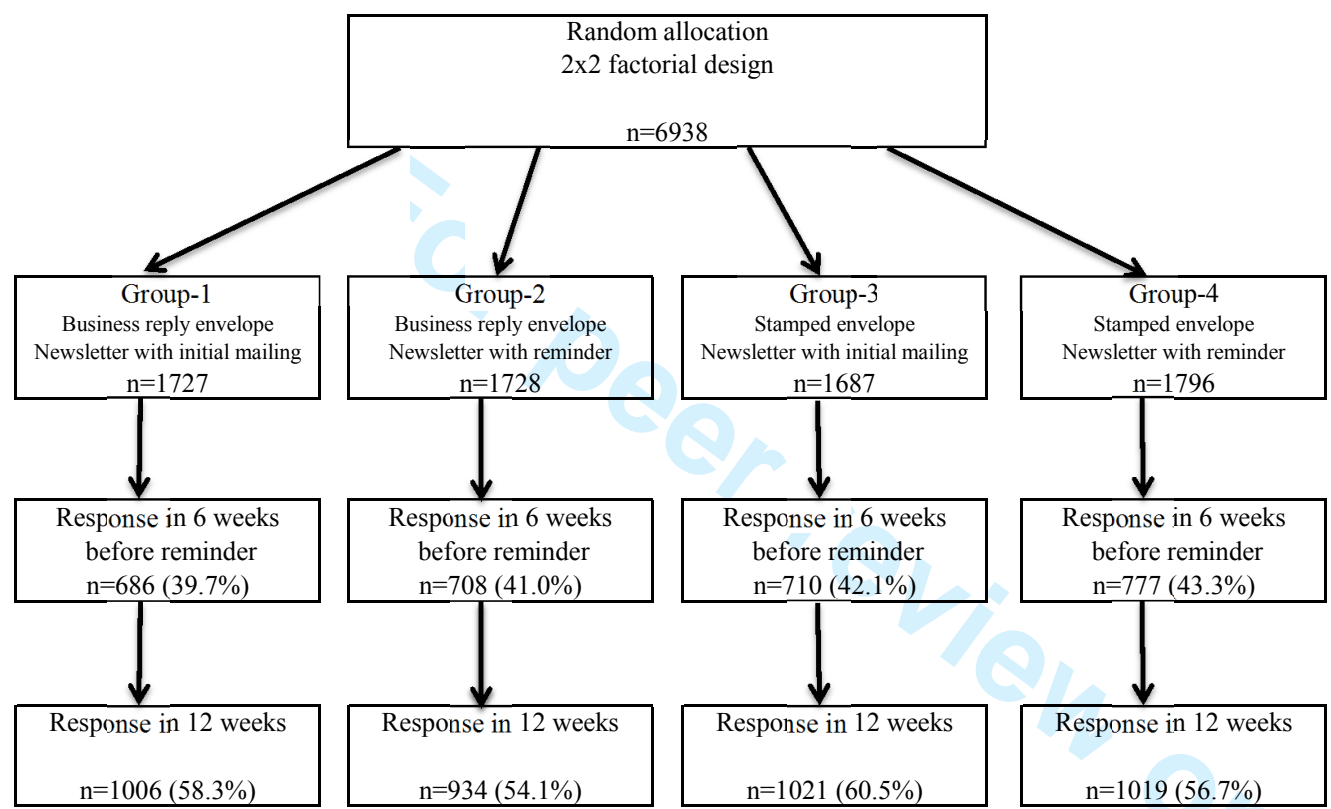


Figure 1 Diagram of cumulative response proportion by allocation group

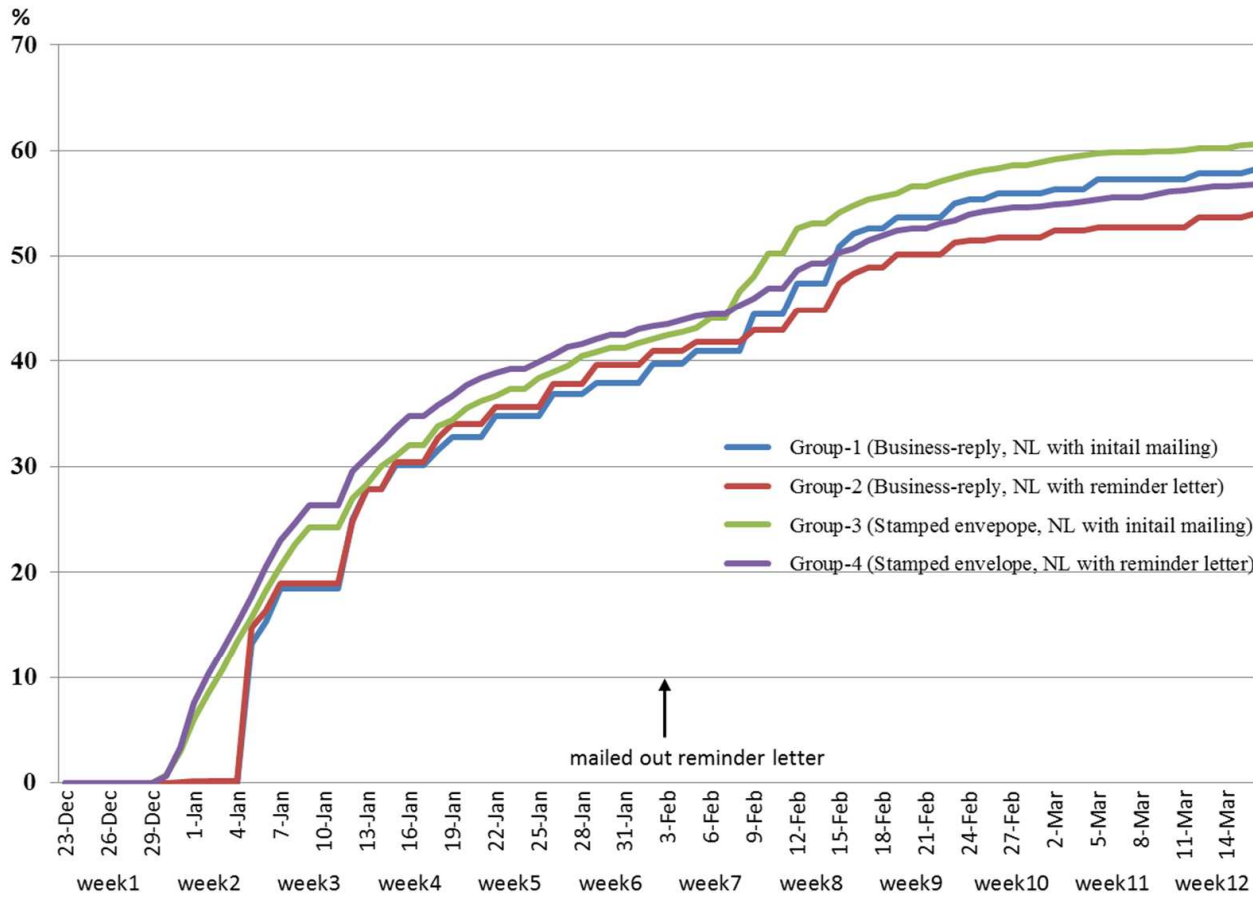


Figure 2 Cumulative response by randomly allocated group

Table 1. Demographic characteristics of the participants

| | Group-1 | Group-2 | Group-3 | Group-4 |
|--------------------------------------|-----------------------------|-----------------------|-----------------------------|----------------------|
| Type of return envelop | business reply | business reply | stamped | stamped |
| Timing of newsletter delivery | with initial mailing | with reminder | with initial mailing | with reminder |
| | n=1,727 | n=1,728 | n=1,687 | n=1,796 |
| Age at survey (years) | | | | |
| Mean \pm SD | 49.7 \pm 7.5 | 49.7 \pm 7.5 | 50.0 \pm 7.6 | 50.2 \pm 7.7 |
| Nursing license | | | | |
| Registered nurse | 1412 (81.8%) | 1446 (83.7%) | 1390 (82.4%) | 1487 (82.8%) |
| Licensed nurse | 118 (6.8%) | 111 (6.4%) | 114 (6.8%) | 127 (7.1%) |
| Midwives | 162 (9.4%) | 136 (7.9%) | 152 (9.0%) | 151 (8.4%) |
| Public health nurse | 25 (1.4%) | 27 (1.6%) | 17 (1.0%) | 22 (1.2%) |
| Unknown | 10 (0.6%) | 8 (0.5%) | 14 (0.8%) | 9 (0.5%) |
| Work | | | | |
| Working | 1599 (92.6%) | 1600 (92.6%) | 1565 (92.8%) | 1644 (91.5%) |
| Not working | 108 (6.3%) | 110 (6.4%) | 102 (6.0%) | 131 (7.3%) |
| Unknown | 20 (1.2%) | 18 (1.0%) | 20 (1.2%) | 21 (1.2%) |
| Region of residence | | | | |
| Hokkaido | 22 (1.3%) | 31 (1.8%) | 28 (1.7%) | 28 (1.6%) |
| Tohoku | 192 (11.1%) | 188 (10.9%) | 183 (10.8%) | 207 (11.5%) |
| Kanto | 284 (16.4%) | 272 (15.7%) | 260 (15.4%) | 264 (14.7%) |
| Hokuriku_Koshin | 267 (15.5%) | 243 (14.1%) | 260 (15.4%) | 255 (14.2%) |
| Tokai | 139 (8.0%) | 165 (9.5%) | 143 (8.5%) | 163 (9.1%) |
| Kinki | 269 (15.6%) | 245 (14.2%) | 272 (16.1%) | 248 (13.8%) |
| Cyugoku | 140 (8.1%) | 157 (9.1%) | 142 (8.4%) | 161 (9.0%) |
| Shikoku | 136 (7.9%) | 125 (7.2%) | 132 (7.8%) | 154 (8.6%) |
| Kusyu | 250 (14.5%) | 280 (16.2%) | 240 (14.2%) | 285 (15.9%) |
| Okinawa | 28 (1.6%) | 22 (1.3%) | 27 (1.6%) | 31 (1.7%) |
| Type of residence area ¹⁾ | | | | |
| Urban | 308 (17.8%) | 321 (18.6%) | 323 (19.1%) | 342 (19.0%) |
| Non-urban | 1419 (82.2%) | 1407 (81.4%) | 1364 (80.9%) | 1454 (81.0%) |
| Smoking ²⁾ | | | | |
| Smoker | 187 (10.8%) | 184 (10.6%) | 194 (11.5%) | 195 (10.9%) |
| Non smoker | 1537 (89.0%) | 1541 (89.2%) | 1485 (88.0%) | 1597 (88.9%) |
| Unkown | 3 (0.2%) | 3 (0.2%) | 8 (0.5%) | 4 (0.2%) |
| Drinking ²⁾ | | | | |
| < 3 days a week | 1286 (74.5%) | 1275 (73.8%) | 1261 (74.7%) | 1359 (75.7%) |
| \geq 3 days a week | 402 (23.3%) | 402 (23.3%) | 387 (22.9%) | 398 (22.2%) |
| Unknown | 39 (2.3%) | 51 (3.0%) | 39 (2.3%) | 39 (2.2%) |
| Pregnancy ²⁾ | | | | |
| Pregnant | 13 (0.8%) | 15 (0.9%) | 21 (1.2%) | 21 (1.2%) |
| Not pregnant | 1702 (98.6%) | 1709 (98.9%) | 1651 (97.9%) | 1763 (98.2%) |
| Unkown | 12 (0.7%) | 4 (0.2%) | 15 (0.9%) | 12 (0.7%) |
| Menopause ²⁾ | | | | |
| Postmenopausal | 603 (34.9%) | 617 (35.7%) | 625 (37.0%) | 690 (38.4%) |
| Premenopausal | 1103 (63.9%) | 1099 (63.6%) | 1046 (62.0%) | 1079 (60.1%) |
| Unkown | 21 (1.2%) | 12 (0.7%) | 16 (0.9%) | 27 (1.5%) |
| Participation in previous survey | | | | |
| Wave II | 1506 (87.2%) | 1509 (87.3%) | 1490 (88.3%) | 1592 (88.6%) |
| Wave III | 1425 (82.5%) | 1429 (82.7%) | 1378 (81.7%) | 1485 (82.7%) |
| Wave IV | 1357 (78.6%) | 1366 (79.1%) | 1364 (80.9%) | 1431 (79.7%) |

1): urban areas are Tokyo metropolitan area and other 19 large cities designated by government ordinance

2): data in latest available survey

Table 2. Odds ratios for cumulative response of questionnaires in 12 weeks

| | Unadjusted | | Age-adjusted | |
|--|------------|-----------------|--------------|-----------------|
| | odds ratio | 95% CI | odds ratio | 95% C.I. |
| Interventions | | | | |
| Type of return envelope | | referent | | referent |
| Business-reply return envelope | 1.10 | (1.00 - 1.21) | 1.09 | (0.995 - 1.20) |
| Stamped return envelope | | | | |
| Timing of newsletter delivery | | referent | | referent |
| With reminder mailing | | | | |
| With initial mailing | 1.18 | (1.07 - 1.29) | 1.18 | (1.07 - 1.30) |
| Demographic and lifestyle factors | | | | |
| Age at survey (for one year increase) | 1.02 | (1.01 - 1.03) | - | |
| Nursing license | | | | |
| Registered nurse | | referent | | referent |
| Licensed nurse | 0.879 | (0.728 - 1.06) | 0.780 | (0.643 - 0.946) |
| Midwives | 0.932 | (0.786 - 1.10) | 0.934 | (0.788 - 1.11) |
| Public health nurse | 1.65 | (1.06 - 2.59) | 1.67 | (1.06 - 2.62) |
| Work | | | | |
| Not working | | referent | | referent |
| Working | 0.802 | (0.658 - 0.976) | 0.886 | (0.725 - 1.08) |
| Region of residence | | | | |
| Hokkaido | 1.66 | (1.08 - 2.54) | 1.64 | (1.07 - 2.52) |
| Tohoku | 1.02 | (0.848 - 1.23) | 0.986 | (0.817 - 1.19) |
| Kanto | | referent | | referent |
| Hokuriku Koshin | 0.976 | (0.821 - 1.16) | 0.937 | (0.787 - 1.12) |
| Tokai | 1.03 | (0.842 - 1.26) | 0.988 | (0.807 - 1.21) |
| Kinki | 0.968 | (0.814 - 1.15) | 0.959 | (0.806 - 1.14) |
| Cyugoku | 0.967 | (0.790 - 1.18) | 0.925 | (0.755 - 1.13) |
| Shikoku | 0.977 | (0.794 - 1.20) | 0.956 | (0.775 - 1.18) |
| Kysyuu | 0.856 | (0.721 - 1.02) | 0.828 | (0.697 - 0.983) |
| Okinawa | 0.620 | (0.417 - 0.923) | 0.593 | (0.398 - 0.883) |
| Type of residence area ¹⁾ | | | | |
| Not urban | | referent | | referent |
| Urban | 1.14 | (1.01 - 1.29) | 1.17 | (1.03 - 1.32) |
| Smoking | | | | |
| Non-smoker | | referent | | referent |
| Smoker | 0.624 | (0.536 - 0.726) | 0.634 | (0.545 - 0.738) |
| Drinking | | | | |
| < 3 days a week | | referent | | referent |
| ≥ 3 days a week | 0.907 | (0.810 - 1.02) | 0.896 | (0.800 - 1.00) |
| Pregnancy ²⁾ | | | | |
| Not pregnant | | referent | | referent |
| Pregnant | 1.05 | (0.651 - 1.69) | 1.26 | (0.776 - 2.03) |
| Menopause ²⁾ | | | | |
| Not postmenopausal | | referent | | referent |
| Postmenopausal | 1.52 | (1.37 - 1.68) | 1.52 | (1.30 - 1.78) |
| Participation in previous survey | | | | |
| Wave II not participated | | referent | | referent |
| participated | 2.08 | (1.79 - 2.40) | 2.01 | (1.74 - 2.33) |
| Wave III not participated | | referent | | referent |
| participated | 7.08 | (6.11 - 8.22) | 7.00 | (6.03 - 8.12) |
| Wave IV not participated | | referent | | referent |
| participated | 17.7 | (14.9 - 21.1) | 17.5 | (14.7 - 20.9) |

1): urban areas are Tokyo metropolitan area and other 19 large cities designated by government ordinance

2): data in latest available survey

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Table 3. Costs of business-reply envelope returns and stamped envelope returns

| | Scenario-1 | | | | | | Scenario-2 | | | | | |
|---|-------------------------|--------|------------|-------------------------|--------|------------|-------------------------|--------|------------|-------------------------|--------|------------|
| | business-reply envelope | | | Stamped return envelope | | | business-reply envelope | | | Stamped return envelope | | |
| | response rate = 50% | | | response rate = 55% | | | response rate = 80% | | | response rate = 88% | | |
| | Unit cost | Number | Total cost | Unit cost | Number | Total cost | Unit cost | Number | Total cost | Unit cost | Number | Total cost |
| Cost of Mailing | | | | | | | | | | | | |
| Postal cost for mailing out survey packet | ¥120 | 10,000 | ¥1,200,000 | ¥120 | 10,000 | ¥1,200,000 | ¥120 | 10,000 | ¥1,200,000 | ¥120 | 10,000 | ¥1,200,000 |
| Stamp for return envelope | | | | ¥120 | 10,000 | ¥1,200,000 | | | | ¥120 | 10,000 | ¥1,200,000 |
| Cost for post-payment by the recipient | ¥135 | 5,000 | ¥675,000 | | | | ¥135 | 8,000 | ¥1,080,000 | | | |
| Total cost | | | ¥1,875,000 | | | ¥2,400,000 | | | ¥2,280,000 | | | ¥2,400,000 |
| Number of responses | | | 5,000 | | | 5,500 | | | 8,000 | | | 8,800 |
| Cost per response | | | ¥375 | | | ¥436 | | | ¥285 | | | ¥273 |



CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|----------------------------------|---------|---|---------------------|
| Title and abstract | | | |
| | 1a | Identification as a randomised trial in the title | 0 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 0 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 1 |
| | 2b | Specific objectives or hypotheses | 1 |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 2 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | 2 |
| Participants | 4a | Eligibility criteria for participants | 2 |
| | 4b | Settings and locations where the data were collected | 2 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 2 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 3 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | 3 |
| Sample size | 7a | How sample size was determined | 2 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 2 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 2 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 2 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 2 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those | |

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|----|--------------------------|---|----------|
| 1 | | | |
| 2 | | assessing outcomes) and how | |
| 3 | | | |
| 4 | | 11b If relevant, description of the similarity of interventions | |
| 5 | Statistical methods | 12a Statistical methods used to compare groups for primary and secondary outcomes | 3 |
| 6 | | 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses | 3 |
| 7 | | | |
| 8 | Results | | |
| 9 | Participant flow (a | 13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and | 3 |
| 10 | diagram is strongly | were analysed for the primary outcome | |
| 11 | recommended) | 13b For each group, losses and exclusions after randomisation, together with reasons | 3 |
| 12 | Recruitment | 14a Dates defining the periods of recruitment and follow-up | 2 |
| 13 | | 14b Why the trial ended or was stopped | |
| 14 | | | |
| 15 | Baseline data | 15 A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| 16 | Numbers analysed | 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was | Figure 1 |
| 17 | | by original assigned groups | |
| 18 | | | |
| 19 | Outcomes and | 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its | 4 |
| 20 | estimation | precision (such as 95% confidence interval) | |
| 21 | | 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended | |
| 22 | Ancillary analyses | 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing | 4 |
| 23 | | pre-specified from exploratory | |
| 24 | | | |
| 25 | Harms | 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | |
| 26 | | | |
| 27 | Discussion | | |
| 28 | Limitations | 20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 6 |
| 29 | Generalisability | 21 Generalisability (external validity, applicability) of the trial findings | 6 |
| 30 | Interpretation | 22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 4-5 |
| 31 | | | |
| 32 | Other information | | |
| 33 | Registration | 23 Registration number and name of trial registry | |
| 34 | Protocol | 24 Where the full trial protocol can be accessed, if available | |
| 35 | Funding | 25 Sources of funding and other support (such as supply of drugs), role of funders | 6 |
| 36 | | | |

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38 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

39 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

40 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Effect of stamped reply envelopes and timing of newsletter delivery on response rates of mail survey: A randomised controlled trial in a prospective cohort study

Abstract

Objective To examine the effects of stamped reply envelope and the timing of newsletter distribution.

Design A randomized controlled trial in a prospective cohort study with a 2x2 factorial design of two interventions.

Setting The Japan Nurses' Health Study (JNHS), a prospective cohort study for women's health.

Participants The present study included 6,938 women who were part of the first-year entry cohort for the fifth wave of the biannual follow-up survey of the JNHS.

Intervention The participants were randomly allocated into four groups; Group-1 (business-reply, newsletter with initial mailing), Group-2 (business-reply, newsletter with reminder), Group-3 (stamped envelopes, newsletter with initial mailing), and Group-4 (stamped envelopes, newsletter with reminder). The thank-you and reminder letters were mailed out at the end of the sixth week. This study was censored at the end of 12 weeks.

Main outcome measures Main outcome measures were cumulative response at the end of six and twelve weeks after mailing out the questionnaire.

Results The cumulative response at twelve weeks were 58.3% for Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 ($p=0.001$). The odds of the response was higher for stamped envelopes than for business-reply envelopes (OR [95%CI]=1.10[1.00-1.21]). The odds was higher for newsletter delivery with initial mailing than for with reminder (1.18[1.07-1.29]). The response in first six weeks for stamped envelope was significantly higher than for business-reply envelope ($p=0.047$). Although the response in six weeks for women received the newsletter with initial mailing was lower than for women who did not, the proportions did not differ significantly ($p=0.291$).

Conclusions The style of return envelope affected response rates of mail-survey. The results of this study suggest that practices of provision of the additional information, should be handled individually in advance, as a separate event from sending follow-up questionnaire or reminder letters.

INTRODUCTION

The Japan Nurses' Health Study (JNHS) is a nationwide prospective occupational cohort study to explore women's health in Japan¹. The JNHS was designed as a prospective study, which consists of a cross-sectional baseline survey that includes a 6-year entry period from 2001 to 2007, and a 10-year follow-up study, from 2001 to 2017¹. For a prospective cohort study, maintaining the cohort, that is, maintaining high follow-up response rates is a major issue. A cohort study is used to estimate risks, rates, or occurrence times of events, and thus requires that the whole cohort remain under observation for the entire follow-up period². Loss of subjects during the study period lowers the validity of the study, because it makes estimation more difficult due to unknown outcomes of lost subjects. Prospective cohort studies that take many years are likely to experience difficulties with locating people over the study period². Follow-up studies that maintain less than about 60% of subjects are considered insufficient to provide confident estimates².

In an effort to achieve high response rates, offering incentives to respondents has become prevalent. A systematic review of 292 surveys showed that both monetary and non-monetary incentives improved the odds of returning the questionnaire³. Also, prior studies reported that the odds of receiving responses were increased when post-office stamped reply envelopes were used compared with enclosing pre-paid business reply envelopes³, although the results were mixed.⁴ Furthermore, sending advance letters has been shown to increase response rates, as well as providing follow-up contacts such reminder letters, telephone contacts, and providing nonrespondents with a second copy of the questionnaire^{3,5,6,7}. In addition, a study has reported that sending a cover letter that asks recipients to decline participation within 7 days if they do not want to participate, raises response rates⁸. Yet, using information leaflets upon recruitment did not affect the number of participants in the survey⁹.

As far as the JNHS is concerned, follow-up questionnaires are mailed to the cohort along with a newsletter. The newsletters are designed to update participants on new information about women's health and the progress of the JNHS. Women who do not respond to the first mailed questionnaire receive a second mailing within 6 months. Subsequently, women who still do not respond receive a third and fourth questionnaire. If the JNHS coordination center cannot contact participants by mail, the JNHS Follow-up Committee confirms if the subject has moved, and a questionnaire is sent to the new address, which is obtained from the resident registry of the corresponding local district.

In the present study, drawing on data from the fifth wave of the JNHS, we examined whether and how stamped reply envelopes compared to business reply envelopes and the timing of newsletter delivery affected the odds of a response. In Japan, studies that receive public funds are not allowed to offer incentives or stamped reply envelopes to survey participants as participants may not respond, and such a practice is regarded as a waste of research expenses for a study supported by the national government. However, for the JNHS it is expected that the use of stamped envelopes and delivery of a newsletter will have favorable effects on response rates. It is hoped that because the present study population draws from

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3 a homogeneous cohort consisting of healthcare professionals, information regarding women's health in
4 general and results of previous JNHS surveys would encourage participant involvement in the study.
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8 **METHODS**

9 **Objectives**

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11 The primary objective of the study was to examine whether stamped reply envelopes and
12 enclosed newsletter improve response rates of mail survey by a 2x2 factorial randomised controlled trial in
13 the Japan Nurses' Health Study cohort. The secondary objective was to explore the demographic and
14 lifestyle factors that affect response rate of mail survey in a women cohort.
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17 **Participants**

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19 The JNHS consists of a cross-sectional baseline survey that includes a 6-year entry period, from
20 2001 to 2007 and a 10-year follow-up study, from 2001 to 2017. The study population was designed for
21 female registered nurse, licensed practical nurses, public health nurses, and/or midwives, who were at
22 least 30 years of age and resident in Japan. Although the participants were licensed to practice nursing,
23 they did not necessarily function as nurses. The baseline survey includes 49,927 responses from
24 participants in Japan. Among them, 14,844 women signed an informed consent form and participated in
25 the follow-up survey. Institutional review boards of Gunma University and the National Institute of Public
26 Health reviewed and approved the JNHS study protocol. The study design of the JNHS has been presented
27 elsewhere¹. The present study included 6,938 women who were in the first-year entry cohort for the
28 fifth-wave follow-up survey of the JNHS.
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34 **Intervention**

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36 To estimate the effect of types of return envelope and timing of newsletters, women were
37 randomly allocated into the four groups with a 2x2 factorial design. For Groups 1 and 2, business-reply
38 return envelopes for post-payment by the recipient were enclosed, and for Groups 3 and 4, stamped return
39 envelopes were provided. In terms of timing of newsletter delivery, for Groups 1 and 3, the newsletter was
40 enclosed when the questionnaires were mailed out; for Groups 2 and 4, the newsletters were sent with the
41 reminder letters. The questionnaires were mailed to participants on December 22, 2009, and a thank-you
42 and reminder letter was mailed out to all respondents, (regardless of whether they had already returned
43 their self-administered questionnaires to the data center) at the end of the sixth week (February 2, 2010).
44 The present study was censored at May 16, 2010 (12 weeks or 84 days). Sample size was determined by
45 the size of the available cohort. With an expected number of 3469 (i.e. 6938/2) per group, and a reference
46 response rate of 60%, for 80% power and 5% significance, the detectable difference in response rate was
47 $\pm 3.3\%$.
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54 When the participants registered at baseline survey, the sequential unique 7-digit ID numbers
55 were assigned randomly by the JNHS data center. According to the ID numbers, participants were
56 allocated to the four groups. The allocated group number for each participant was the remainder when the
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3 ID number was divided by four.

4 5 **Measurements**

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7 Primary outcome measure was cumulative response proportion at 12 weeks after
8 mailing out the questionnaire. Secondary outcome measure was cumulative response at the end
9 of 6 weeks after initial mailing, just before delivering the reminder letters.

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11 The participants were simultaneously randomised to two interventions: type of return
12 envelope (business reply vs. stamped return envelopes) and timing of newsletter delivery
13 (newsletter with initial mailing vs newsletter with reminder). Besides these two variables, following
14 demographic and lifestyle variables were used to explore the factors affecting response rates: age at the
15 survey, type of nursing license (registered nurse, licensed nurse, midwives, and public health nurse),
16 region of residence (Hokkaido, Tohoku, Kanto, Hokuriku_Koshin, Tokai, Kinki, Cyugoku, Shikoku,
17 Kyusyu, and Okinawa), and type of residence area (urban [Tokyo metropolitan area and other 19 large
18 cities designated by government ordinance] and not-urban area), work status (not-working and working),
19 smoking status (smoking and not-smoking), alcohol drinking (< 3 days a week and \geq 3 days a week),
20 pregnancy (pregnant and not-pregnant), menopausal status (postmenopausal and others). All the data were
21 obtained from the available latest wave of survey. These variables included factors previously studied^{10, 11,}
22¹² and reproductive health related issues in women.

23 24 25 **Statistical Analysis**

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27 Characteristics of participants were compared between groups using ANOVA and chi-square test
28 to check the relevance of randomization process. Before examining main effect of two interventions, type
29 of return envelope (business reply vs stamped) and timing of newsletter provision (with initial mailing vs.
30 with reminder) on cumulative response proportion at 6 and 12 weeks after initial mailing, the interaction
31 of these two interventions was tested by logistic regression model. The main effects of the interventions
32 were tested by chi-square test. In order to examine the factors affecting the responses in 12 weeks after
33 initial mailing, logistic regression models were used to estimate unadjusted and age-adjusted odds ratios
34 (ORs) and their 95% confidence intervals (CIs). For all statistical analysis, SAS Ver. 9.1 (SAS Institute,
35 North Carolina, USA) was used and $p < 0.05$ was set as statistically significant.

36 37 38 **RESULTS**

39 40 41 **Characteristics of Participants**

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43 Of the 6938 women of the first-year entry JNHS cohort, 1727, 1728, 1687, and 1796 women
44 were randomised into Group-1, Group-2, Group-3, and Group-4, respectively (figure 1). With the
45 questionnaire, 3455 received business-reply return envelopes and 3483 women were provided with
46 stamped envelopes. A total of 3414 women received the newsletter with initial mailing and 3524 women
47 received the newsletter with thank-you and reminder mailing. The four groups did not differ significantly
48 in demographic and lifestyle characteristics (table 1).

Cumulative response proportion by group

The cumulative response proportions at 12 weeks were 58.3% for women in Group-1, 54.1% for Group-2, 60.5% for Group-3, and 56.7% for Group-4 (figure 1), and these proportions significantly differed among the groups ($\chi^2=15.5$; d.f.=3; $p=0.001$). There was not statistically significant interaction effect of two interventions, type of enclosed return envelope and timing of newsletter delivery, on the proportions ($p=0.881$). The response for women who received stamped reply envelopes (Groups-3 and 4) was 58.6%, and it was significantly higher compared with the proportion of 56.2% for those who received business-reply envelopes (Groups-1 and 2) ($\chi^2=4.15$; d.f.=1; $p=0.042$). With respect to the effect of newsletter, the cumulative response proportion at 12 week when the newsletter was delivered at initial mailing was significantly higher than the response when the newsletter was delivered with thank-you and reminder letters ($\chi^2=11.1$; d.f.=1; $p<0.001$); 59.4% for Group-1 and 3 and 55.4% for Group-2 and 4.

We compared the cumulative proportions at 6 weeks to confirm the main effects of interventions without the effect of reminder mailing (figure 2). The proportion at 6 weeks for business-reply envelopes (Groups-1 and 2) was 40.3% and the proportion for stamped reply envelopes (Groups-3 and 4) was 42.7%, and those proportions differed significantly ($\chi^2=3.93$; d.f.=1; $p=0.047$). The proportion for women received the newsletter with initial mailing (Group-1 and 3) was 40.9% and the proportion for women who did not receive it with initial mailing (Group-2 and 4) was 42.1%, and these proportions did not differ significantly ($\chi^2=1.11$; d.f.=1; $p=0.291$).

Factors affecting response

The ORs and 95% CIs for cumulative responses at 12 weeks are shown in Table 1. With respect to two interventions, unadjusted ORs showed statistically significant effects. The stamped envelopes raised the response by 10% relative to provision of business-reply envelopes (OR [95%CI] = 1.10 [1.00 - 1.21]), and the newsletter delivery with initial mailing raised the response by 18% relative to the delivery with reminder letters (1.18 [1.07 - 1.29]). However, when adjusted by age at the survey, the effect of stamped return envelopes became not significant (table 2).

Regarding other factors that showed significant effects on the response by age-adjusted analyses, nursing license, region of residence, type of residence area, smoking, menopause, and participation in previous survey were associated with the odds of response.

DISCUSSION

Timing of newsletter delivery and type of return envelope

Results of the present study showed that provision of the newsletters with the questionnaires tended to decrease the odds of returning the self-administered questionnaire. In addition, if the newsletters were provided to participants 6 weeks later with reminder letters, it would further keep participants (non-responders at that point) from returning their questionnaires. Thus, the results suggest that each practice, such as provision of information, request for collaboration, and encouragement of contribution,

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3 should be managed individually, as separate events in advance. As prior studies^{3, 10, 14} documented that
4 advanced contacts via letters, cards, and phone calls increase the rates, if the update of the survey is
5 offered via newsletter to respondents in advance, it may facilitate their understanding of the research
6 issues and then improve response rates as well as enhance the quality of responses by reducing the number
7 of items left blank or incomplete and decreasing inconsistent answers.
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11 In the light of cost-performance, some studies suggest that allocating large sums of money to
12 achieve high response rates may not always significantly improve the quality of the sample^{13, 14, 15}. Prior
13 studies documented that with properly high response rates (approximately 70%), the bias due to
14 non-response was unlikely to affect estimation of the survey^{13, 14, 15}. However, for a follow-up cohort
15 survey like the JNHS, maintaining high follow-up response rates is crucial to maintaining the cohort.
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19 Provision of a stamped return envelope had a significant effect of raising the odds of returning
20 the questionnaire in the JNHS follow-up survey. Although there is an argument that providing stamped
21 return envelopes is an inappropriate use of research expenses (especially for research with public funds)
22 and is not cost-beneficial, it depends on the survey response rates that you expect to achieve. We should
23 discuss about the cost-performance based on the results of an actual cost analysis¹⁶. If we assume
24 provision of stamped return envelopes, compared to business-reply envelopes for post-payment by the
25 recipient, increases the response rate by 10%, in a case survey of 10,000 participants, when the response
26 rate with business-reply envelope is 50%, assuming that the stamped return envelope approach can
27 improve the odds of response by 10%, the business-reply approach is better in terms of cost-performance
28 (table 3). However, if the response rate is 80% in a survey of 10,000 participants, mailing costs for the
29 stamped return envelope approach and for business reply envelope approach will be 285 yen/response and
30 273 yen/response, respectively. Consequently, if the response rate is as high as 80%, the stamped return
31 envelope approach will be more advantageous than the business-reply envelope approach in terms of
32 cost-performance. In that case, providing stamped return envelopes is the best way for the JNHS to
33 maintain the cohort with a better cost-performance.
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42 **Other factors affecting the response**

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44 In addition to the effect of the type of return envelope and timing of the newsletter, the present
45 analysis showed interesting points with regard to factors predicting the response to the survey.
46 Participation in a previous survey increased the odds of responding to this survey. In particular,
47 participants who were involved in the most recent survey were 18 times more likely to return the
48 questionnaire (table 2). In addition, there appeared to be some differences in women's responses to the
49 survey based on their residence regions. As shown in table 2, women living in Hokkaido were more likely
50 than those living in Kanto to respond to the survey. In contrast, women living in Kyusyu and Okinawa
51 were less likely to respond to the survey
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56 Women who experienced menopause were more likely to participate in the present survey, even
57 after the odds was adjusted by age. The questionnaire of the JNHS included several items with respect to
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3 reproductive health-related issuers, such as pregnancy and menopause. Recognizing the association of the
4 research issues with women's personal experiences would promote their involvement in the study. In
5 contrast, smokers in the previous survey were less likely to respond to the present questionnaire. Given a
6 recent negative image of smoking and the public trends against smoking, smokers would be reluctant to
7 answer questions with regard to their health. However, if this tendency becomes prominent, health effects
8 of smoking could be underestimated, especially in later surveys.

13 **Limitations**

14 There are several limitations to the present study. A major one refers to generalization of results.
15 The cohort of the JNHS follow-up survey consists of female healthcare professionals with a nursing
16 license who agreed to participate in the survey by signing an informed consent form. It may be
17 problematic to apply the results of the present analysis to a broader population. There is, however, a major
18 advantage of the present analysis. The JNHS is a nationwide occupational cohort study in Japan, and
19 drawing on data from the cohort study, we could randomly allocate items of research interest, that is, type
20 of return envelopes and timing of newsletter delivery, within the survey population.

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