

1 **Effect of request for unique personal identifiers and souvenir incentives on**
2 **consent to health record linkage: evidence from an RCT nested within a cohort**

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ABSTRACT

Objective: It is unclear if unique personal identifiers should be requested from participants for health record linkage: this permits high-quality data linkage but at the potential cost of lower consent rates due to privacy concerns.

Study Design and Setting: Drawing from a sampling frame based on the FAMILY Cohort, using a 2x2 factorial design, we randomly assigned 1,200 participants to: (1) request for Hong Kong Identity Card number (HKID) or no request, and (2) receiving a souvenir incentive (valued at USD4) or no incentive. The primary outcome was consent to health record linkage. We also investigated associations between demographics, health status, and postal reminders with consent.

Results: Overall, we received signed consent forms from 33.3% (95% CI 30.6% to 36.0%) of respondents. We did not find an overall effect of requesting HKID (-4.3%, 95% CI -9.8% to 1.2%) or offering souvenir incentives (2.4%, 95% CI -3.1% to 7.9%) on consent to linkage. In subgroup analyses, requesting HKID significantly reduced consent among adults aged 18-44 years (OR 0.53, 95% CI 0.30 to 0.94, compared to no request). Souvenir incentives increased consent among women (OR 1.55, 95% CI 1.13 to 2.11, compared to no souvenirs).

Conclusions: Requesting a unique personal identifier or providing a souvenir incentive did not affect overall consent to health record linkage.

Keywords: Health record linkage; Data linkage; Consent; Randomised; Unique identifier; Incentive

What is new?

- Overall, requesting a unique personal identifier or providing a souvenir incentive did not significantly affect consent to health record linkage. Thus in this context, unique personal identifiers should be requested to enable higher precision in health record linkage.
- However, the effect of the interventions varied by age and sex: younger respondents were less likely to provide consent when asked to provide a unique personal identifier, whereas incentives increased consent among young people and women.
- Postal invitations may still be a relatively inexpensive, useful initial strategy to obtain consent for health record linkage.

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1 INTRODUCTION

2 As participation rates continue to decline for academic research, government or
3 industry surveys (1), data linkage to administrative and medical records provides an
4 important alternative to access routinely collected data while minimising respondent
5 burden (2). Yet low consent rates to health record linkage and response bias are
6 frequent challenges (2-4). Age (5-9), ethnic minority status (6, 7, 10, 11), education level
7 (5, 7, 8), household income (5, 6), area of residence (6, 10), health status (5, 7, 12),
8 chronic metabolic diseases (5), depressive symptoms (12), and health services
9 utilisation (7) have been associated with consent, although inconsistencies remain (7-9,
10 11, 12). In addition, while cash incentives appear to increase response to mail surveys
11 or other survey modalities (13-16), it is unclear whether incentives influence consent
12 for data linkage (17), and whether souvenir incentives are effective.

13

14 Data linkage can be achieved in two ways. Deterministic linkage uses a unique personal
15 identifier - such as the Hong Kong Identity Card number (HKID), or the Social Security
16 number in the US or the National Health Service number in the UK - to link information
17 contained in different datasets. The advantage of a unique identifier is higher health
18 record linkage success. However, HKID numbers are also used in banking services and
19 as authentication for password changes, thus are generally regarded as sensitive
20 personal data (18). Privacy concerns have been shown to be negatively associated with
21 consent in observational studies (19, 20). The second option, probabilistic linkage, uses
22 personal data such as name and date of birth to circumvent the need for unique
23 personal identifiers but may result in duplicate matches. The choice is therefore
24 unclear: unique personal identifiers permit high quality data linkage but at the potential
25 cost of lower consent rates. We accordingly tested the effect of 1) requesting a unique

1 personal identifier and 2) providing a small, souvenir incentive on consent to health
2 record linkage, using a randomised factorial design. A secondary objective was to
3 identify whether respondent characteristics and the use of postal reminders were
4 related to consent.

5

6 **METHODS**

7 **Study design and participants**

8 We nested a randomised controlled trial within the FAMILY Cohort (total N = 46,001), a
9 population-based longitudinal study described in detail elsewhere (21). Participants
10 were drawn from a subsample of the FAMILY Cohort where one member from each
11 household was randomly selected to form the sampling frame. Eligibility was defined
12 by age ≥ 18 years and completion of two waves of in-person follow-ups. We used a 2-by-
13 2 factorial design to randomly assign 1,200 adult participants to: (1) request for
14 personal unique identifier (HKID) or no request, and (2) receive a souvenir incentive or
15 no incentive. Randomisation sequence was created using Stata MP 13.1 (StataCorp,
16 College Station, TX), and was stratified by sex, age group and educational attainment
17 (Figure 1). All participants were blinded to the randomised design. The study was
18 approved by the Institutional Review Board of the University of Hong Kong/Hospital
19 Authority Hong Kong West Cluster.

20

21 All respondents received identical invitation letters, an information leaflet, a consent
22 form and a prepaid return envelope by mail. For respondents allocated to receive HKID
23 requests, their consent form included a box to fill in their HKID and, as an alternative, a
24 secure web link to enter the HKID (Figure 1). Either was accepted. Those allocated to
25 receive a souvenir incentive were mailed an upfront souvenir including a FAMILY

1 Cohort-branded washcloth, a set of chopsticks and a rice paddle, with a collective value
2 of USD~4. Two reminder letters were sent 20 days and 33 days after the initial mailing.
3 We allowed 60 days as the cut-off period for return of completed consent forms.
4

5 **Primary analysis**

6 The primary outcome was receipt of written consent to health record linkage by
7 intention-to-treat. We needed an overall sample size of 1,188 ($\alpha = 0.025$ and power
8 = 0.90) for the 2 factorial comparisons (hence, overall $\alpha = 0.05$ and power = 0.81) in
9 order to detect a 10% absolute difference in consent proportion between (1) HKID
10 request vs. no request, and (2) souvenir incentive vs. no incentive (22). The expected
11 consent proportion for the control group was 35%. We used the chi-square test to
12 compare the proportions consenting between the four groups. We then used
13 multivariable logistic regression and the likelihood ratio test to perform interaction
14 analyses to test whether the effect of requesting HKID varied according to whether
15 participants were randomly assigned to receive a souvenir incentive. Similarly, we
16 performed tests for interactions between the interventions and demographic subgroups
17 (age, sex, education level and household income) by adding treatment subgroup
18 interaction terms to the models.
19

20 **Secondary analyses**

21 We assessed associations between baseline predictors assessed at wave 2 including
22 demographics and health status (physical and mental well-being using the SF-12v2 (23,
23 24), chronic disease status and hospital admission) with consent using multivariable
24 logistic regression with Bonferroni correction for multiple comparisons. Each baseline

1 predictor was examined in a separate regression model, adjusting for age, sex,
2 education level, employment status and household income.

3
4 Additionally we examined whether the two postal reminders were associated with a
5 significant change in the daily consent rates using segmented logistic regression (25).

6 All analyses were done using R version 3.3.0.

7

8 **RESULTS**

9 Participants (n=1,200) were randomly allocated into four groups: 1) HKID request and
10 incentive (n=292); 2) HKID request without incentive (n=306); 3) incentive without
11 HKID request (n=303); 4) no incentive and no HKID request (n=299). Baseline
12 characteristics were balanced in the four groups (Table 1).

13

14 *Consent by group*

15 The proportions consenting were, in descending order, 36.6% (95% CI 31.2%-42.3%)
16 in the group with an incentive and without a HKID request, 34.1% (28.8%-39.8%) in the
17 control group receiving no incentive and no HKID request; 32.2% (26.9%-37.9%) in the
18 group receiving both incentive and request, and 30.1% (25.0%-35.5%) among the
19 group receiving HKID request without an incentive. There was no interaction between
20 the two interventions (P=0.96).

21

22 *Effect of HKID request*

23 Participants in the two groups that received an HKID request had a 4.3% lower absolute
24 consent (31.1%, 95% CI 27.4%-35.0%) compared to those not asked to give their ID
25 (35.4%, 95% CI 31.6%-39.3%); the difference was not significant (P=0.14).

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Effect of souvenir incentive

Those who received a souvenir incentive had a 2.4% higher absolute consent proportion (34.5%, 95% CI 30.6%-38.4%) compared to those without the incentive (32.1%, 95% CI 28.4%-35.9%); this difference was also not significant (P=0.38).

Interaction between demographics and interventions

Subgroup analysis shows that the effect of requesting the HKID varied according to age, where requesting HKID reduced consent proportions among younger adults but not among middle-aged or older adults (Figure 2). Provision of a souvenir incentive increased consent proportions among young adults and women (Figure 3).

Demographic correlates of giving consent

In the overall sample, older age and higher household income were associated with consent to health records linkage (Table 2). However, only age remained significant after correction for multiple comparisons. Other demographic characteristics and indicators of health status were not associated with consent.

Effect of postal reminders

There were clear temporal associations of receiving completed consent forms with each of the two reminder mailings (Figure 4, upper panel). Seven breakpoints in the daily consent rate were identified over time (Figure 4, lower panel). The daily consent rate increased substantially after the third (Day 20) and the fifth (Day 32) breakpoints, which correspond to the first and the second postal reminders.

1 **DISCUSSION**

2 We did not find an overall effect of requesting a unique personal identifier on consent to
3 health record linkage. However, younger respondents were less likely to provide
4 consent when asked to provide HKID (Figure 2), which is consistent with younger
5 individuals having more privacy concerns about health record linkage (8, 26).

6 Comparison of responders and non-responders showed that older age was associated
7 with consent (Table 2). There were no systematic differences regarding other
8 demographic characteristics or health status.

9

10 We also did not find an overall effect of providing a souvenir incentive on consent,
11 although incentives increased consent among younger people and women (Figure 3).

12 The effect of the interventions did not vary by socioeconomic status. Our overall null
13 effect for incentives could be attributed to the use of souvenirs rather than monetary
14 incentives (13-15, 27). In addition, the incentives may not have increased consent
15 proportions as participants were drawn from a cohort that has previously received
16 similar incentives over a number of years.

17

18 Possible reasons for the low consent rate in our study include the use of postal
19 invitations. Postal invitations are less costly but yield lower response rates compared to
20 face-to-face interviews (28). Our level of consent is comparable to previous studies
21 using postal invitations for health record linkage (3, 4). Moreover, a multi-ethnic
22 national cohort study found that individuals of Asian ethnicity are less likely to consent
23 with health records linkage (10). However, the study also identified higher educational
24 attainment to be negatively associated with consent (10). The inconsistent findings for

1 socioeconomic status and health status as predictors of giving consent suggest that
2 these associations could be contextually specific (7-9, 11, 12).

3

4 Our findings are subject to certain limitations. First, our trial was powered to detect a
5 10% difference between groups and thus would not be expected to detect smaller effect
6 sizes as in the present study. Second, as the randomised trial was nested within a
7 cohort, our findings may have limited generalisability to *de novo* studies that are
8 contacting participants for the first time. In those settings, the effect of requesting
9 unique personal identifiers and provision of incentives may be larger. However, our
10 original sample was randomly drawn from the community and therefore generalisable
11 to other population-based studies.

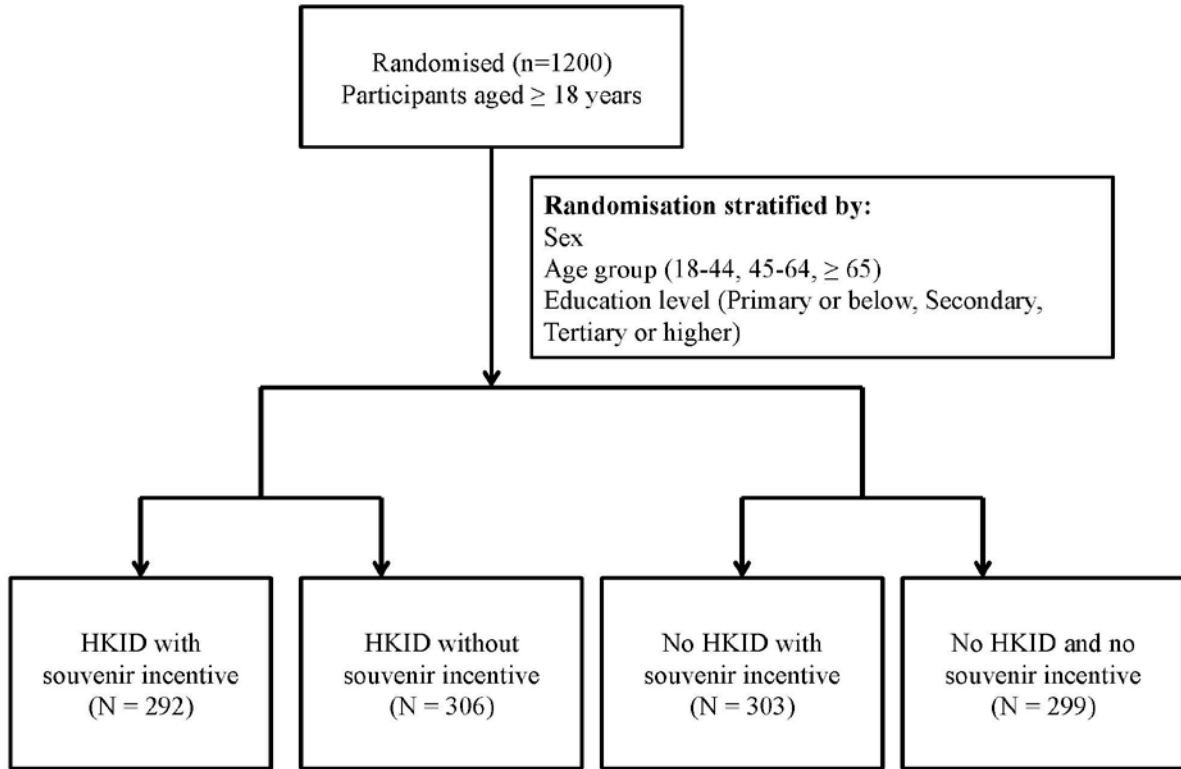
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13 In conclusion, our trial demonstrated that the request for a unique personal identifier
14 did not substantially reduce consent proportions. Our findings add to the literature on
15 demographic variation in study participation (1), in that there may well be age-based
16 variability for providing sensitive identifying information. Although only one-third of
17 those approached consented to health record linkage, postal invitations could still be a
18 relatively inexpensive, useful initial strategy for cohort studies.

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2 **FIGURE LEGENDS**

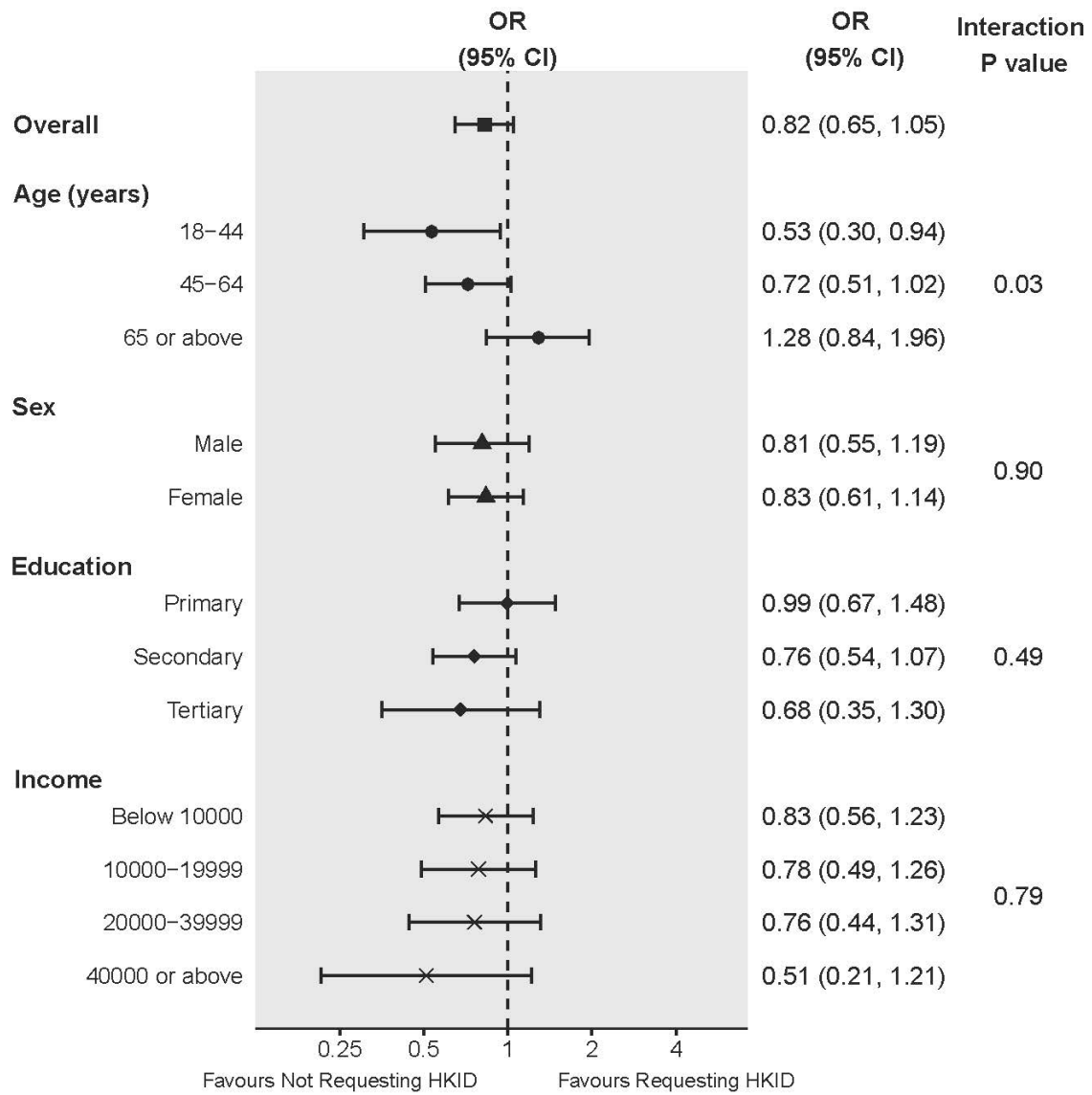
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5 **Figure 1. Randomised Allocation of Request for Hong Kong Identity Card number**
6 **(HKID) and Souvenir Incentive.**

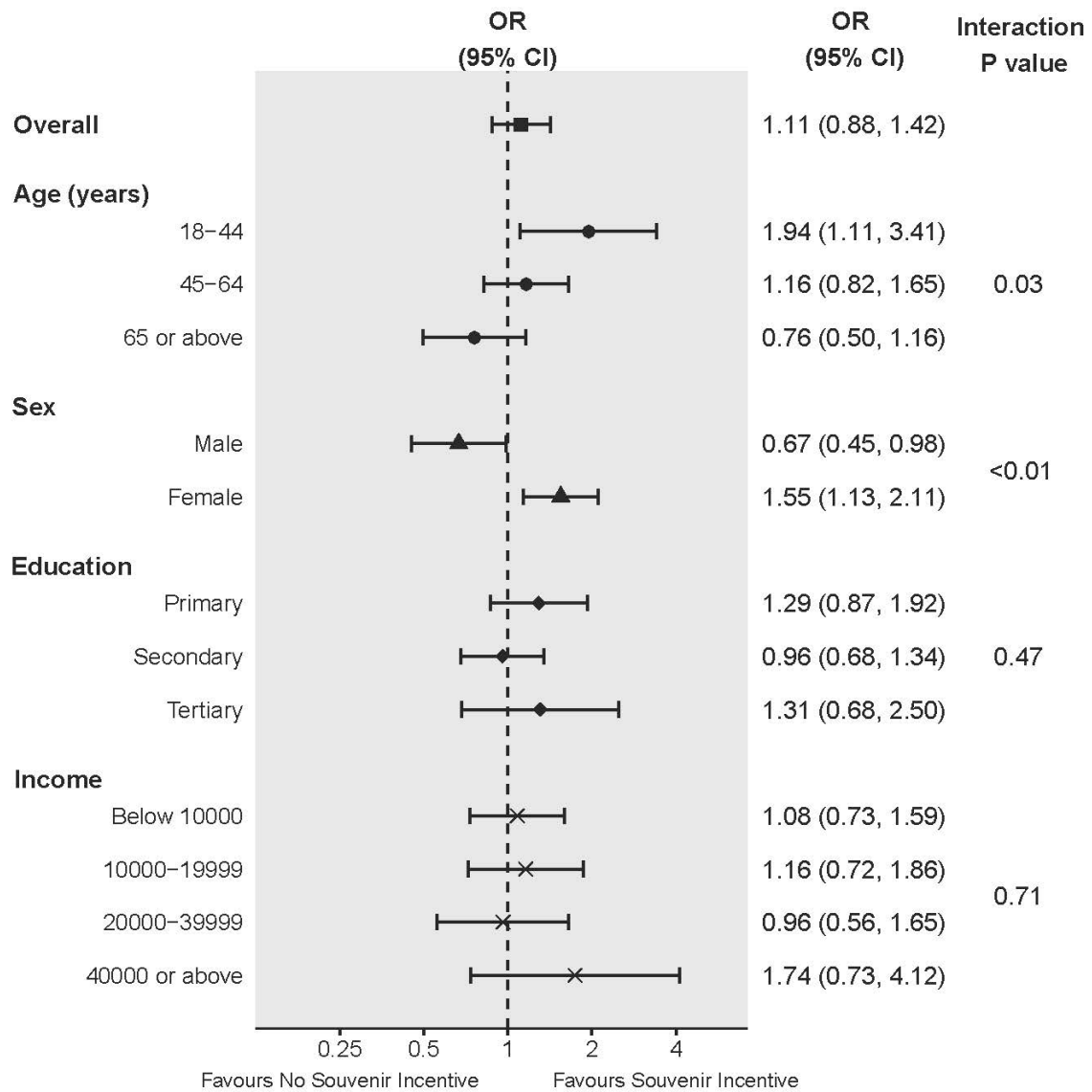
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Figure 2. Effect of Requesting Hong Kong Identity Card number (HKID) According to Demographic Subgroups. P values were obtained from the likelihood ratio tests of the interaction terms of requesting HKID and the subgroups.



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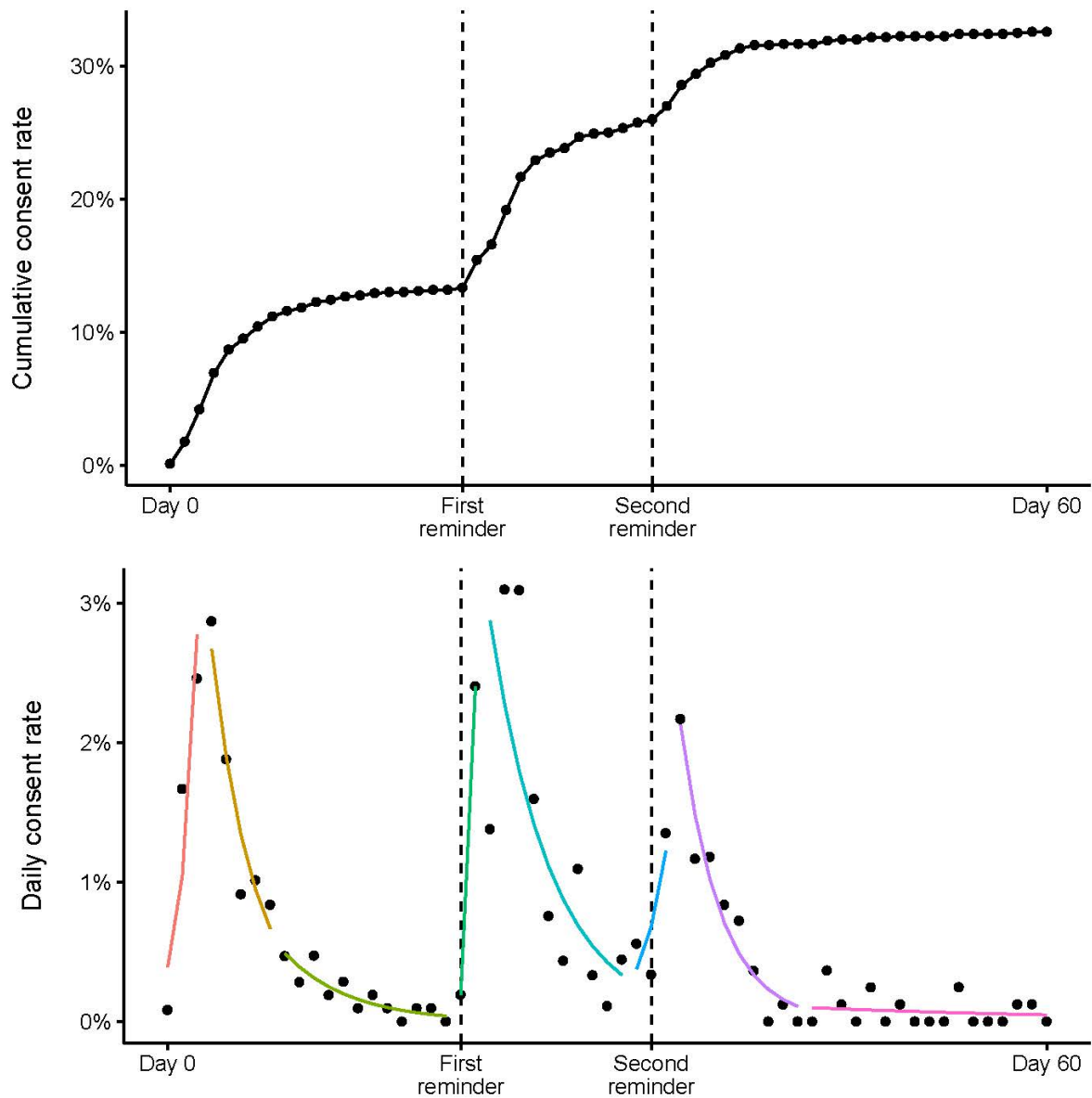
2 **Figure 3. Effect of Providing Souvenir Incentives According to Demographic**

3 **Subgroups.** P values were obtained from the likelihood ratio tests of the interaction

4 terms of souvenir incentives and the subgroups.

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Figure 4. Cumulative and Daily Consent Rates. The upper panel shows the temporal associations of receiving completed consent forms with each of the two reminder mailings. The lower panel shows time points where there was a change in daily consent rates as indicated by breakpoints between fitted lines.

Table 1. Baseline Characteristics of the Study Participants

	HKID request				No HKID request			
	Incentive		No incentive		Incentive		No incentive	
	No.	%	No.	%	No.	%	No.	%
Female sex	182	62.3	188	61.4	188	62	186	62.2
Age group, years								
18-44	70	24.0	75	24.5	74	24.4	72	24.1
45-64	131	44.9	135	44.1	135	44.6	135	45.2
≥ 65	91	31.2	96	31.4	94	31.0	92	30.8
Educational attainment								
Primary	106	36.3	111	36.3	110	36.3	109	36.5
Secondary	145	49.7	149	48.7	147	48.5	146	48.8
Tertiary	41	14.0	46	15.0	46	15.2	44	14.7
Employment status								
Economically inactive	159	54.6	161	52.8	159	52.5	163	54.5
Unemployed	7	2.4	4	1.3	3	1.0	5	1.7
Employed	125	43.0	140	45.9	141	46.5	131	43.8
Monthly income (HKD)								
<10000	111	41.4	115	39.2	126	46.3	125	46.8
10000-19999	78	29.1	82	28.0	80	29.4	70	26.2
20000-39999	56	20.9	70	23.9	46	16.9	53	19.9
≥40000	23	8.6	26	8.9	20	7.4	19	7.1

Abbreviation: HKID, Hong Kong Identity Card number.

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Table 2. Association of Demographics and Health Status with Consent to Health Record Linkage

Baseline predictors	N	Consent %	Model 1		Model 2	
			OR	95% CI	OR	95% CI
<i>Demographics</i>						
Female sex [†]	744	32.3%	0.89	0.70, 1.14	-	-
Age group, years [†]						
18-29	94	9.6%	1.00	-	-	-
30-44	197	28.9%	3.85	1.89, 8.68	-	-
45-59	423	35.0%	5.08	2.62, 11.12	-	-
60-74	307	40.7%	6.49	3.31, 14.29	-	-
≥75	179	33.5%	4.76	2.34, 10.76	-	-
Education level						
Primary	436	33.3%	1.00	-	1.00	-
Secondary	587	34.4%	1.05	0.81, 1.37	1.13	0.83, 1.55
Tertiary	177	29.4%	0.83	0.57, 1.22	1.52	0.91, 2.55
Employment status						
Economically inactive	642	32.4%	1.00	-	1.00	-
Unemployed	19	31.6%	0.96	0.33, 2.47	1.12	0.37, 3.04
Employed	537	34.3%	1.09	0.85, 1.39	1.25	0.90, 1.74
Monthly household income (HKD)						
<10000	477	30.8%	1.00	-	1.00	-
10000-19999	310	33.2%	1.12	0.82, 1.52	1.18	0.84, 1.65
20000-39999	225	37.8%	1.36	0.98, 1.90	1.52	1.05, 2.20
≥40000	88	39.8%	1.48	0.92, 2.36	1.53	0.90, 2.58
<i>Health status</i>						
Physical well-being (0 - 100)	-	-	1.00	0.98, 1.01	1.00	0.98, 1.02
Mental well-being (0 - 100)	-	-	1.00	0.98, 1.01	1.00	0.98, 1.01
Diagnosed with chronic metabolic or psychiatric disorders ^a						
No	876	32.6%	1.00	-	1.00	-
Yes	324	34.9%	1.10	0.84, 1.44	0.95	0.70, 1.29
Admitted to a hospital in past year						
No	1114	33.7%	1.00	-	1.00	-
Yes	86	27.9%	0.76	0.46, 1.23	0.77	0.46, 1.28

Abbreviation: OR, Odds ratio; CI, Confidence interval.

Model 1: unadjusted

Model 2: adjusted for age, sex, education level, employment status and household income

[†] We present unadjusted models only for age and sex as other covariates could not be common causes of these exposures and outcomes

^a Self-reported doctor-diagnosed chronic metabolic diseases (hypertension, diabetes and hyperlipidaemia) or psychiatric disorders (depression, anxiety disorder or schizophrenia)

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