Age, Sex and Sexual Orientation Effects in the Safetxt Trial: Secondary Data Analysis of a Randomized Controlled Trial

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ABSTRACT

Background

Increasing rates of sexual transmitted infections (STIs) and antimicrobial resistance among young people underscore the urgent need for preventative interventions. Interventions should be evidence-based and tailored to the unique risks and needs associated with varying age, sex and sexual orientation. We used data from the Safetxt trial to explore whether young people's age, sex and sexual orientation influence a) their risk of STI re-infection and condom use and b) the effect of the Safetxt intervention on STI re-infection and condom use.

Methods

We conducted exploratory secondary analyses of data from the Safetxt trial that evaluated a theorybased digital sexual health intervention tailored according to sex and sexual orientation. We recruited 6248 young people with STIs from 92 UK sexual health clinics and assessed outcomes after one year, including the cumulative incidence of STI re-infection and condom use at last sex. We used adjusted logistic regression and margins plots to visualise effect modification.

Results

There were differences in STI re-infection and condom use by age, sex and sexuality. Age was associated with STI re-infection (OR 0.90, 95% confidence interval (CI) 0.87-0.94) with evidence for interaction between age and sexuality (p<0.001). Our findings suggest that the risk of STI re-infection decreases with age among young heterosexuals but increases among men-who-have-sex-with-men (MSM). Overall, MSM had the highest likelihood of re-infection (OR 3.53, CI 2.66-4.68) despite being more likely to use condoms (OR 1.50, CI 1.18-1.91).

Among MSM, age modified the intervention effect on condom use at one-year with highest benefits among participants aged 16-18, moderate to minor benefits among those aged 18-21 and no effect among participants aged 22-24 years.

Conclusions

Future digital health interventions tailored for diverse sexuality groups need to target young people early enough to have an impact on sexual behaviour. Specific novel interventions are needed for older MSM.

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KEY MESSAGES

What is already known on this topic

The Safetxt intervention increased condom use among 16-24 years olds diagnosed with chlamydia, gonorrhoea, or non-specific urethritis in the UK.

People in younger age categories(<24 or <19 years, according to studies in Australia, New Zealand, and Canada) and men-who-have-sex-with-men (according to a Spanish study) are more likely to experience STI re-infection.

What this study adds

In the UK, among people aged 16-24 diagnosed with chlamydia/ gonorrhoea or non-specific urethritis:

- Overall STI re-infection within a year decreased by 10% for every one-year increase in age at the time of the index infection.
- However, the opposite pattern was observed among men-who-have-sex-with-men (MSM), whereby re-infection at one year increased with age. Women-who-have-sex-with-men (WSM) are more likely than men-who-have-sex-with-women (MSW) to experience STI re-infection and are less likely to use condoms.
- MSM are more likely than MSW to experience STI reinfection, despite being slightly more likely to use condoms.
- Age modifies the effect of the Safetxt intervention on condom use among MSM, with largest benefits for MSM aged 16-18 and no effect in MSM aged 22-24 years.

How this study might affect research, practice or policy

Service providers should consider implementing the condom promotion elements of the Safetxt intervention, especially among MSM aged under 20 years.

Novel interventions are needed to meet the needs of older MSM and other sexuality groups, including WSM.

INTRODUCTION

Sexually transmitted infections (STIs) remain a major global health problem, with burden and trends diverging across age, sex and sexual orientation¹⁻⁴ In the UK, recent data show concerning upwards trends for the most common STIs, especially among young people². For example, gonorrhoea rates in 2022 were the highest since records began in 1918, with people aged 15-24 years most affected. Chlamydia detection rates among young women increased by 22% between 2021 and 2022. Menwho-have-sex-with-men (MSM) and men-who-have-sex-with-men-and-women (MSMW) continue to experience disproportionately high STI rates.⁵ As antimicrobial resistance threatens STI treatment, effective STI prevention interventions for higher-risk age, sex and sexual orientation groups become even more critical⁶.

In light of current efforts to develop a coherent, cross-sector sexual health strategy², it is crucial to determine the effects of interventions for diverse target groups based on age, sex and sexual orientation.

The Safetxt trial evaluated the effects on STIs of a behavioural intervention delivered by text message ('Safetxt') compared to a control group among people aged 16-24 in the UK. It was a parallel-group, individual-level, randomised superiority trial in which care providers and outcome assessors were blinded to allocation. The Safetxt intervention was tailored according to sex and sexual orientation⁷. At one-year post-enrollment, the intervention increased condom use (OR 1·14, 95% Cl 1·01- 1·28), but there were no benefits to STI re-infection.

A qualitative study among Safetxt participants partly explained the unexpected results. Feedback from control group participants implied a strong Hawthorne effect with trial participation and control group messages triggering safer sex behaviour, which might have diminished observable intervention effects on STI re-infection rates⁸⁹. Many participants also thought that the intervention would be more useful for younger age groups. In addition, some participants (from both intervention and control group) suggested that it was partly due their increased age and 'becoming more mature' that they had changed their behaviour, irrespective of receiving the intervention⁸.

The Safetxt trial's prespecified sub-group analyses for the primary outcome (STI re-infection), did not detect variations by age, sex or sexual orientation¹⁰. However, these analyses used a binary age variable (16-19 versus 20-24 years), potentially losing information¹¹. In addition, we have not conducted subgroup analyses for the condom use outcome. Using the Safetxt dataset, we aimed to:

Objective 1

a. Determine whether age and 'sexuality group' of people enrolled in the Safetxt trial are associated with.

i. STI re-infection (cumulative incidence of objectively confirmed STI re-infection at 12 months)

ii. condom use (condom use at last sexual encounter self-reported at 12 months)

b. Examine whether age may be an effect modifier for the association between 'sexuality group' and the outcomes.

Objective 2

Determine whether young people's age and 'sexuality group' modify the effect of the Safetxt intervention on

i. STI re-infection (adding further depths to previously reported results)

ii. condom use

METHODS

Study design and sample

For this secondary data analysis, we used the Safetxt trial data set with 6248 participants recruited from 92 UK sexual health clinics. Eligibility criteria were people aged 16-24, diagnosed with or treated for chlamydia, gonorrhea, or non-specific urethritis in the last two weeks, who owned a mobile phone.^{7 12 13}

The Safetxt intervention

The Safetxt intervention was developed based on behavioral theory and with strong user involvement⁷ ¹⁰. Automated text messages, sent to participants over one year, aimed to reduce STI re-infection by increasing partner notification, condom use and STI testing before sex with a new partner. Message content was tailored by sex, sexual orientation, and the index STI diagnosed. An interactive component allowed participants to request further texts on particular topics.

Control group participants received monthly text messages requesting information about address changes. (See Supplementary file 1 for message examples.)

Measures

Full details of trial measures assessed at all time points are reported elsewhere^{7 12 13}. Below, we list measures relevant to this analysis.

Baseline measures

Socio-demographic measures self-reported at baseline included age at randomisation (continuous), ethnicity, sex/gender identity (female, male, non-binary), and sex/gender of previous sexual partners. We created a 'sexuality group' variable with sub-groupings pre-specified in the trial Statistical Analysis Plan (SAP) for the sub-group analyses¹⁴: women-who-have-sex-with-men (WSM, including womenwho-have-sex-with-men-and-women), men-who-have-sex-with-women-only (MSWo), and MSM (including MSMW). Due to data sparsity, we omitted sub-groupings with non-binary people and women-who-have-sex-with-women-only (WSWo). As a measure of socioeconomic status based on area of residence, we used adjusted Indices of Multiple Deprivation (IMD) for use across the UK¹⁵ (quintiles 1 and 2 (least deprived), quintile 3, quintiles 4 and 5 (most deprived)).

In addition, types of STI (chlamydia and/or gonorrhea and/or non-specific urethritis; not known) and self-reported condom use at last sexual intercourse (yes-no), were recorded at baseline.

Outcome measures

The primary trial outcome was the cumulative incidence of objectively confirmed chlamydia or gonorrhoea re-infection at 12 months (referred to as 'STI re-infection' throughout this paper). Re-infection was assessed using self-sampling kits for chlamydia and gonorrhoea that were posted to all respondents at 12 months. Additionally, for all participants, data on STI tests completed during the 12 months follow-up period and their results were collected from all recruiting clinics. If participants self-reported accessing STI testing at other services (i.e. sexual health clinics other than the recruiting clinic or a GP), that service was contacted to verify the diagnosis.

Self-reported secondary outcomes were assessed by postal paper-based questionnaire or the trial web-based data entry form depending on participants' preferences. The only secondary trial outcome considered for our current study is 'condom use at last sexual encounter' measured at 12 months, as it was the only prespecified secondary trial outcome for which a significant intervention effect could be shown^{12 13}.

Statistical analysis

We computed all analyses using Stata 18, apart from supplementary figure S1, which we generated in R 4.2. We used the complete case Safetxt dataset, including only participants who had complete primary outcome data. For the primary trial analyses, we had used multiple imputation by chained equations to impute missing outcome data, however these results had been very similar to those

obtained after secondary complete case analysis^{12 13}. All statistical tests and confidence intervals (CI) were two-sided with significance considered at the 0.05 level and CI at the 95% level.

Objective 1

We used multivariable logistic regression analyses on the complete dataset to examine associations of age and sexuality with re-infection and condom use, adjusted for intervention allocation. We adjusted analyses for the baseline covariates pre-specified in the SAP for the main Safetxt trial analyses¹⁴, including type of STI, ethnicity, and age or sexuality group (for associations with sexuality or age group respectively). We also adjusted for IMD, because of increased STI risk in more deprived areas^{5 16 17}. We report adjusted odds ratios (AOR), the 95% CI (CI) and p-values (from likelihood ratio test, LRT).

We examined whether age modified associations between sexuality and outcome variables by including an interaction term in the multivariable logistic regression models. Where interaction was identified (p<0.05), we present a margins plot to visualise the effect modification. The assumption that the models for objective 1 are correctly specified were based on qualitative research linked to the Safetxt trial⁸ and literature⁵. Additionally, we completed post-estimation tests, including link tests for model specification¹⁸ and Pearson and Hosmer–Lemeshow goodness-of-fit tests¹⁹. We tested for multicollinearity by computing variance inflation factors (VIF) and tolerance values (1/VIF), with values greater than 0.2 interpreted as indication of multicollinearity²⁰. Multicollinearity naturally induced through the inclusion of an interaction term was accepted if it led to a better model. We also tested for influential cases via Pregibon's lambda beta hat influence statistics¹⁸.

Objective 2

We used the data set with allocation groups to examine whether age, sex and sexuality modified the effect of the Safetxt intervention on the two outcomes. All analyses were by intention to treat. When comparing the outcome in each trial arm using logistic regression we adjusted for the same baseline covariates that had been pre-specified in the SAP for the main Safetxt trial analyses¹⁴, including type of STI at baseline, ethnicity, and age or sexuality group (for associations with sexuality or age group

respectively). These covariates had been purposively selected, using knowledge from previous studies, and excluding variables that could potentially lead to collinearity^{13 14 21}.

The Safetxt trial was powered to detect intervention effects for the overall sample only. There was no evidence that the effect of the intervention on the primary outcome was different in any of the prespecified subgroups, including sexuality and age groups (16-19 years; 20-24 years)^{12 13}. Here we conduct subgroup analyses for the condom use outcome and assess heterogeneity of treatment effect across the subgroups with a test for interaction using logistic regression.

We also examined potential modifying effects of age on both outcomes within each of the three sexuality groups by including an interaction term in the multivariate logistic regression models. We used age as a continuous rather than binary variable to avoid losing information¹¹. Where interaction was identified (LRT, p<0.05), we created a margins plot to visualise the effect modification.

Patient and public involvement

Patient advisory focus groups informed the trial questions, intervention design, design of data collection materials and procedures, and there was one patient and public involvement member in the Trial Steering Committee. The objectives of this secondary analysis were informed by the analyses of open feedback comments by 3526 Safetxt participants and interviews with 18 Safetxt participants after the trial^{8 10}.

RESULTS

Follow-up was completed between May 2016 and February 2020. Primary outcome data (STI reinfection over 12 months) were available for 78% (n=3126/4028) of WSM, 67% (n=1045/1568) of MSWo and 78% (n=463/593) of MSM and condom use outcome data for 81% (n=3254/4028) of WSM, 69% (n=1088/1568) of MSWo and 80% (n=477/593) of MSM.

Table 1 reports baseline socio-demographic and sexual-health related variables by sexuality group and allocation arm. For each of the sexuality groups, participant characteristics were similar between intervention and control group.

Table 1 – Baseline characteristics of Safetxt participants by sexuality group and treatment allocation

Sexuality group		WSM (including WSMW)		MSWo only		MSM (including MSMW)	
Treatment allocation	Intervention	Con	trol	Intervention	Control	Intervention	Control
	N=2026, n (%)	N=2	2002 <i>,</i> n (%)	N=790 <i>,</i> n (%)	N=778, n (%)	N=275 <i>,</i> n (%)	N=318, n (%)
Age group							
16-19	874 (43)	825	(41)	247 (31)	227 (29)	52 (19)	52 (16)
20-24	1152 (57)	117	7 (59)	543 (69)	551 (71)	223 (81)	266 (84)
Ethnicity							
White British/ Other White background	1585 (78)	157	3 (79)	597 (76)	603 (78)	222 (81)	240 (76)
Black/Black British - Caribbean/African/other	228 (11)	212	(11)	128 (16)	108 (14)	19 (7)	21 (7)
Asian/Asian British- Bangl./Chinese/Indian/Pakist	ani/other 55	5 (3) 55 (3)	20 (3)	14 (2)	14 (5)	22 (7)
Mixed background	125 (6)	134	(7)	32 (4)	42 (5)	14 (5)	28 (9)
Other background	33 (2)	28 (1)	13 (2)	11 (1)	6 (2)	7 (2)
Index of Multiple Deprivation quintile ^a	[N=2010]	[N=	1986]	[N=783]	[N=769]	[N=274]	[N=314]
1 and 2 - least deprived	636 (32)	585	(29)	247 (32)	261 (34)	68 (25)	100 (32)
3	394 (20)	388	(20)	154 (20)	147 (19)	51 (19)	52 (17)
4 and 5 - most deprived	980 (49)	101	3 (51)	382 (49)	361 (47)	155 (57)	162 (52)
Type of STI at baseline							
Chlamydia	1772 (87)	174	8 (87)	553 (70)	553 (71)	96 (35)	115 (36)
Gonorrhoea	106 (5)	109	(5)	59 (7)	46 (6)	117 (43)	143 (45)
Gonorrhoea and Chlamydia	100 (5)	96 (5)	26 (3)	22 (3)	32 (12)	33 (10)
Gonorrhoea or NSU	4 (0.2)	9 (0	.5)	12 (2)	12 (2)	11 (4)	11 (4)
NSU (non-specific urethritis)	10 (0.5)	9 (0	.5)	101 (13)	106 (14)	13 (5)	8 (3)
don't know	34 (2)	31 (2)	39 (5)	39 (5)	6 (2)	8 (3)
Condom use at last sex							
Yes	432 (21)	456	(23)	178 (23)	193 (25)	128 (47)	147 (46)
No	1558 (77)	152	1 (76)	597 (76)	572 (74)	137 (50)	163 (51)
Unsure	36 (2)	25 (1)	15 (2)	13 (2)	10 (4)	8 (3)

WSM=women-who-have-sex-with-men; WSMW=women-who-have-sex-with-men-and-women; MSWo=men-who-have-sex-with-women-only; MSM=men-who-have-sex-with-men; MSMW=men-who-have-sex-with-men-and-women. Note: participants with non-binary sex-identity and women-who-have-sex-with-women–only are excluded due to low numbers and to avoid empty cells in analyses. Banglaeshi

^a reduced denominator, IMD quintile missing for some participants who provided an invalid postcode.

Objective 1 results

For objective 1a, adjusted logistic regression results showed there is strong evidence that that age was associated with STI re-infection (p<0.001, Table 2). For every one-year increase in age at baseline, participants had a 10% lower odds of STI re-infection (AOR 0.9, CI 0.87, 0.94). There is some evidence that age is also associated with condom use (p=0.03). Every one-year increase in participant age was associated with a 3% decreased odds (AOR 0.97, CI 0.94, 1.00). Table 2 also shows strong evidence of association between sexuality group and both outcomes (p<0.001).

Outcome variable (right)	STI re-infection		Condom use at last sex		
Baseline variable (below)	AOR (95% CI)	p-value	AOR (95% CI)	p-value	
Age	0.90 (0.87, 0.94)	< 0.001	0.97 (0.94, 1.00)	0.033	
Sexuality group					
MSWo	1	< 0.001	1	< 0.001	
WSM (inc. WSMW)	1.24 (1.02, 1.52)		0.70 (0.60, 0.82)		
MSM (inc. MSMW)	3.53 (2.66, 4.68)		1.50 (1.18, 1.91)		

 Table 2 – Associations of age and sexuality variables with STI reinfection and condom use at 1 year

Logistic regression analyses adjusted for other variables in model, including prespecified covariates (baseline STI, ethnicity and Index of Multiple Deprivation) and intervention allocation; p-values from likelihood ratio tests; MSWo=men-who-have-sex-with-women-only; WSM=women-who-have-sex-with-men; WSMW= women-who-have-sex-with-men; MSM=men-who-have-sex-with-men; MSMW=men-who-have-sex-with-men-and-women.

For objective 1b, we tested the strength of evidence for an interaction term between age and sexuality in the two adjusted logistic regression models with a likelihood ratio test. There was no evidence of an interaction between age and sexuality for the condom-use outcome (p=0.67). However, there was strong evidence of interaction between age and sexuality for the STI re-infection outcome (p<0.001). Figure 1 visualises this effect modification and shows that with increasing age, the predicted probability of STI re-infection increased among MSM, but slightly decreased among MSWo and WSM. The likelihood of STI re-infection was similar among the youngest participants, but higher among older MSM compared to older MSWo and WSM.

Objective 2 results

There was no heterogeneity of treatment effect by age or sexuality groups for neither STI re-infection (as reported previously^{12 13}), nor the condom use outcome (joint interaction test p-values: p=0.96 and p=0.29). We present estimates for the intervention effect by sexuality subgroup in supplement Figure S1.

When testing for potential modifying effects of age (as a continuous variable) on both outcomes within each of the three sexuality groups, there was evidence of an interaction (p=0.017) for condom use among MSM (likelihood-ratio test LR chi2(1) = 5.77, p=0.016). Figure 2 visualises the modifying effect of age on condom use at last sex among MSM. Intervention effects are greatest for younger participants (aged 16-18 years), only moderate to minor for the middle age group (aged 19-21 years) and no effects can be seen for older participants (aged 22-24 years). There was no significant interaction among the other groups for either outcome.

DISCUSSION

Both age and sexuality were associated with the cumulative incidence of STI re-infection at one year among young people enrolled in the Safetxt trial. WSM were more like to experience STI re-infection within a year and less likely to use condoms, than MSW. MSM were more likely than MSW to be reinfected with an STI within one year despite being slightly more likely to use condoms. With older age at enrollment, the predicted risk of re-infection with chlamydia or gonorrhoea decreased slightly among WSM and MSWo but increased among MSM. Overall, there was no heterogeneity of the safetxt treatment effect by age or sexual grouping. However, among MSM, age modified the effect of the Safetxt intervention on condom use at one year, with highest effects among youngest participants aged 16-18, moderate to minor effects among those aged 18-21 and no effect among oldest participants aged 22-24 years.

Strengths and limitations

This analysis was conducted on a large, high-quality dataset prospectively collected over the course of one year with objectively measured STI outcomes¹². Other studies often rely on cross-sectional data, passively collected routine data, or short-term self-reported outcomes²²⁻²⁴. Only the condom use outcome was self-reported and could be influenced by social desirability bias. 'Condom use at last sexual encounter' is one of the most frequently used indicators, due to its low risk of recall bias. However, it may not account for consistent condom use over time or variations in condom use with different partners. Including additional measurements of consistent condom use and the number of protected sex acts would have provided a more detailed picture.²⁵ The increased questionnaire length, however, would likely have reduced completion rates.²⁶ Young people's refusal to participate in the trial or complete follow-up questionnaires could lead to potential bias, limiting the generalizability of results. We achieved higher follow-up rates than previous similar trials²⁷, but some potential for bias remains¹⁰.

Compared with the general UK population, those living in more deprived areas with a high IMD and ethnic minorities were well represented in the trial, as were MSM. Although 1568 MSWo took part, they were under-represented and WSM were over-represented. Slightly less STI and condom use outcome data were available for MSWo than for WSM and MSM. Baseline participant characteristics were well balanced between intervention and control groups; nevertheless, we adjusted for prespecified baseline covariates in all analyses, including those on intervention effects. We also adjusted for IMD, based on previous evidence of higher STI risks among people living in more deprived areas^{5 16 17}.

The number of trial participants reporting non-binary sex-identity and WSWo were too low to include in the analysis. We chose the sexuality group and age variables based on evidence from the literature and our qualitative research; nonetheless, due to multiple tests performed and low power of interaction tests, our analyses are explorative only and results should be interpreted with caution.

Interpretation of results and significance of findings

The associations of age and sexuality with STI re-infection in our UK study are consistent with limited recent international evidence regarding the predictors of re-infection. In an observational study in Spain with 9927 participants, repeat STI was more likely in 'gay, bisexual and other MSM' (GBMSM) and in <35 year-olds, but the effects among different age categories under 35 were not explored²⁸. Studies in other high-income countries also found that the likelihood of chlamydia re-infection after repeat testing was highest among youngest age groups (<19 years in studies in Canada²² and New Zealand^{29 30} and <24 years in Australia³¹).

The predictors of re-infection we identified are also consistent with known predictors of infection. Surveillance data in England show that among heterosexuals aged 15-24 years, men are three and women are six times more likely to be diagnosed with an STI than people aged 25 to 64 years⁵. The surveillance data also suggest that MSM (including MSMW) have the highest rates of new STI diagnoses, but the rates peak at a later age compared to WSM and MSW. In 2019, the highest STI rates were recorded at age 15-19 years in WSM (4,780/100,000), 20-24 years in MSW (2,160/100,000) and 25-34 years in 'gay, bisexual and other MSM' (18,630/100,000)⁵.

We also found that MSM had about 3.5 times the odds of STI re-infection, despite a 50% higher odds of condom use at last sex compared to MSWo. The slightly higher condom use among MSM did not seem to compensate for other STI risks such as a greater likelihood of an STI infected partner because of higher STI prevalence in MSM, differences in sexual networks, numbers of concurrent partners and timings between relationships³².

The age differences in re-infection that we identified may be explained by higher rates of partner change among young people³³. Overall, young people are known to have higher levels of partner change, but the levels might peak earlier in heterosexuals than in MSM, possibly due to differences in timing of sexual debut, stigma, or other factors. Reliable data on age at sexual debut usually differentiate by sex, but not by sexuality group³³. However, most recent available national survey data

from 2010-2012 on proportions of people with \geq 2 partners by age, suggest that partner numbers are highest at ages 16-24 among MSWo and WSMo, versus age 25-34 years among MSM³³.

Studies are scarce to which our results on intervention effects could be compared, despite the increasing prominence of digital sexual health interventions^{24 34}. In our recent systematic review, we found that evidence from randomised trials was lacking for the effects of mHealth interventions on STI reinfection²⁴. Subgroup analyses did not identify any differences in intervention effect by age (adult versus adolescents) or sexuality (mixed/all sexualities, MSM, WSM), but the number of participants/ RCTs per subgroup was low.

Our exploratory analyses suggest that the Safetxt intervention had the highest effect on condom use among MSM aged 16-18 years, but lost effectiveness with increasing age at enrollment. This is consistent with our qualitative study where Safetxt participants felt that the intervention would be particularly helpful for younger people, such as secondary school and first year post school⁸. The Safetxt intervention therefore seemed to have targeted younger MSM at the right time but might have been too late or less relevant for older MSM.

Overall, our results suggest that the Safetxt intervention was successfully tailored for younger MSM, and the condom component of the intervention could be implemented among this group. Further research should consider how to address the unmet needs of older MSM and WSW. People with transgender and non-binary sex/gender identities would need to be specifically sampled to design interventions with and for them.

Record levels of gonorrhoea and other STIs in the context of antimicrobial resistance underline the urgency with which the unmet needs highlighted in our study must be addressed². In addition to offering digital interventions early, the development of STI vaccines should remain a key objective. Meanwhile, the targeted (off label) use of the 4CMenB vaccine for the prevention of gonorrhoea could provide some protection against gonorrhoea in MSM and other individuals at higher risk of infection³⁵.

Conclusion

Among people aged 16-24 diagnosed with chlamydia/ gonorrhoea or non-specific urethritis, reinfection decreases with age in heterosexuals, but increases with age in MSM. WSM were more likely to experience STI re-infection within a year and less likely to use condoms than MSW. MSM were more likely than MSW to be re-infected with an STI within one year despite being slightly more likely to use condoms. The Safetxt intervention increased condom use among MSM aged 16-18 years, but not in older age groups of MSM. Digital health interventions need to target young people, especially MSM, early enough to have an impact on sexual behaviour.

Acknowledgments

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Competing Interests

The authors declare that they have nothing to disclose.

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Contributions of authors

CF was the Chief Investigator of the safetxt trial. CF, OLM, FCIH contributed to writing the grant application and design of the safetxt intervention; CF and OLM contributed to the design of the trial; CF, OLM and MJP contributed to the management of data collection. SB conceived the idea for this secondary analysis with input from MJP, CF and FCIH. JRC was one of the trial statisticians, on whose SAP and code some of the analyses in this paper were based. SB conducted the analyses for this study with input from MJP and EB. All authors contributed to the interpretation of results. SB wrote the first draft of the manuscript with input from MJP, CF, FCIH, EB and OLM. All authors commented on revised versions and approved the final manuscript. CF is responsible for the overall content as guarantor and controlled the decision to publish.

Ethics statement

We obtained ethics approval for the trial from the NHS Health Research Authority – London – Riverside Research Ethics Committee (REC reference 15/LO/1665) and the London School of Hygiene & Tropical Medicine (reference 10464). Participants provided informed consent in writing or via the trial website.

Data availability statement

Individual deidentified patient data, including a data dictionary, will be made available via our data sharing portal FreeBIRD website indefinitely. The trial protocol, statistical analysis plan, and trial publications will be available online. The Stata code for the secondary analyses will be made available upon reasonable request.

Figure legends

Figure 1 - Predicted probability of STI re-infection by sexuality group among all Safetxt trial participants *Figure legend:*

Margins plot visualizing the modifying effect of sexuality group on the association between age and STI re-infection at one year; Predictive margins with 95% CI; MSM=men-who-have-sex-with-men; MSMW=men-who-have-sex-with-men-and-women; MSWo=men-who-have-sex-with-women-only; WSM=women-who-have-sex-with-men; WSMW=women-who-have-sex-with-men-and –women.

Figure 2 - Predicted probability of condom use among MSM (including MSMW) by Safetxt trial arm *Figure legend:*

Margins plot visualizing the modifying effect of age on the effect of the Safetxt intervention at one year within the MSM (including MSMW) sub-group; Predictive margins of intervention allocation with 95% Confidence Intervals

Supplementary materials

Supplementary file 1 – Example Safetxt intervention and control group text messages Supplementary file 2 – Figure S1: Effect of Safetxt intervention on condom use at last sexual intercourse by sexuality group

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