Statistical analysis plan for #chatsafe: A randomised controlled trial of an intervention on Young People's Ability to Communicate Safely About Suicide on Social Media

Date and version number:

Version 1. 4 April

ANZCTR Registration Number

ACTRN12622001397707

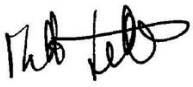
Reference

Robinson J, La Sala L, Cooper C, Spittal M, Rice S, Lamblin M, Brown E, Nolan H, Battersby-Coulter R, Rajaram G, Thorn P, Pirkis J, May-Finlay S, Silenzio V, Skehan J, Krysinska K, Bellairs-Walsh I. Testing the Impact of the #chatsafe Intervention on Young People's Ability to Communicate Safely About Suicide on Social Media: Protocol for a Randomized Controlled Trial. JMIR Res Protoc 2023;12:e44300. doi: 10.2196/44300

SAP revision history

Protocol version	Date	Description and reason for change
Version 1	08/05/2024	

Roles

Name	Role	Affiliation	Signature
Professor Jo Robinson	Lead investigator	Orygen, Centre for Youth Mental Health, The University of Melbourne	
Professor Matthew Spittal	Lead biostatistician	Centre for Mental Health and Community Wellbeing, The University of Melbourne	
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Study design

The study is a pragmatic, parallel, superiority randomized controlled trial. It will be conducted in accordance with the Consolidated Standards of Reporting Trials statement over 18 months. Participants will be 400 young people aged 16-25 years (200 per arm). Participants will be recruited via social media advertising and assessed at 3 time points: time 1 (baseline); time 2 (8-week postintervention commencement); and time 3 (12week postintervention). Participants will be asked to complete a weekly survey to monitor safety and evaluate each piece of social media content. The intervention comprises an 8-week social media campaign including social media posts shared on public Instagram profiles. The intervention group will receive the #chatsafe suicide prevention content and the control group will receive sexual health content. Both groups will receive 24 pieces of content delivered to their mobile phones via text message and email. The primary outcome is safety when communicating on the web about suicide, as measured via the purpose-designed #chatsafe online safety questionnaire. Additional outcomes include willingness to intervene against suicide, internet self-efficacy, safety, and acceptability.

Outcome measure

Outcome measures together with the assessment schedule are presented in Table 1. All participants complete the same questionnaires (T1, T2, T3, and purpose-designed 3-item weekly evaluation and engagement survey) regardless of the arm they are allocated to.

The primary outcome is safety when communicating online about suicide at T2, as measured via the purpose-designed #chatsafe online safety questionnaire. This measure was specifically designed for this purpose by 3 study authors (JR, LLS, and CC).

Secondary outcomes are:

- confidence when communicating on the internet about suicide at T2 and T3, as measured via the purpose-designed #chatsafe online safety questionnaire;
- willingness to intervene against suicide on the internet at T2 and T3, as measured via the Willingness to Intervene Questionnaire;
- internet self-efficacy at T2 and T3, as measured by the Internet Self-Efficacy Questionnaire;
- safety of the weekly #chatsafe content, as measured by the purpose-built weekly evaluation and engagement survey;
- acceptability of the #chatsafe intervention, as measured by the purpose-built T2 evaluation questions; and
- safety of the #chatsafe social media intervention (as a whole), as measured by the number of (or absence of) adverse events recorded throughout the trial.

Participant adverse events include:

- participant response to item 9 on the Patient Health Questionnaire (PHQ-9) at baseline (time 1), time 2, or time 3.
- Participant response to the 9-item weekly evaluation survey indicates distress, measured by participants selecting “very distressed” in response to the question “To what extent did you find the content this week distressing?”
- Participant response to the T2 evaluation questionnaire indicates that a particular piece of campaign content made them feel distressed or at risk of suicide.

- The participant directly contacts the research team via social media or email and reports distress or risk of harm to self. All adverse events will be responded to by the study team, in line with the study's safety management strategy.

Feasibility of the #chatsafe social media intervention was measured by campaign reach via social media analytics, and participant retention or attrition via audit of study enrollment and withdrawal logs. Self-reported evaluations of the acceptability of receiving the #chatsafe social media intervention were measured by purpose-designed study questions.

Exploratory outcomes are as follows:

- subgroup differences (gender, age, previous exposure to, previous experiences of suicide and self-harm, and level of social media usage) at T2 and
- self-reported open-ended evaluations of the safety, feasibility, and acceptability of receiving the PROSPEct social media intervention for sexual health promotion in the control group at T2.

Data management and workflow

The data collected from RedCap will be stored and managed on a secure server restricted to authorised study personnel, and user activity will be logged for audit purposes. To facilitate this blinding process, the data management system will be configured to mask group assignments from all authorized users. Only the independent data manager, who is not involved in the data analysis or outcome assessment, will have access to the full unmasked dataset. All data exported for statistical analysis will have treatment assignments coded as "Group A" and "Group B," without disclosing which group corresponds to the intervention or control.

A robust data validation process will be conducted by the data manager to identify and resolve any potential data issues (e.g., errors and conflicts). The final blinded data will be transferred to external biostatisticians via a secure data transfer channel (e.g., https://filesender.aarnet.edu.au/) to complete data analysis.

Statistical analysis

Data processing

Raw data will be first processed to obtain outcome measures as specified in the study protocol.

Table 1. Study Measures and Variable Coding

Objective	Description	Endpoint	Outcome variable
Primary – (1) **safety** communicating online about suicide	This outcome is measured using the Purpose designed #chatsafe online safety questionnaire (COSQ). Safety is operationalised as adherence to the #chatsafe guidelines and has three domains: 1. Sharing experiences, 2. Responding online and 3. Communicating after a suicide has occurred. It is measured using sets of questions (15-19 items) across three vignettes. Note: a validation study using a different sample is currently underway, which may impact on how this outcome variable is coded unblinding.	Measured at Baseline (T1), Post-intervention (T2) and Follow Up (T3). **Primary endpoint:** Post-intervention (T2)	**Safety** when communicating online about suicide, three domains measured using the #chatsafe online safety questionnaire (COSQ): **Total score Vignette 1 - COSQ_Safety_Sharing:** (item 1 + item 2 + item 3 + item 4 + item 5 + item 6 + item 7 + item 8 + item 9 + item 10* + item 11* + item 12 + item 13* + item 14 + item 15)/15 **Total score Vignette 2 - COSQ_Safety_Responding:** (item 1 + item 2 + item 3 + item 4 + item 5* + item 6 + item 7 + item 8 + item 9 + item 10 + item 11 + item 12 + item 13 + item 14 + item 15 + item 16 + item 17 + item 18 + item 19)/19 **Total score Vignette 3 - COSQ_Safety_BereavedComms:** (item 1 + item 2 + item 3 + item 4 + item 5 + item 6 + item 7 + item 8* + item 9 + item 10 + item 11 + item 12 + item 13 + item 14 + item 15 + item 16 + item 17 + item 18)/18 **COSQ_Safety: COSQ_Safety_Sharing+ COSQ_Safety_Responding+ COSQ_Safety_BereavedComms** * = *reverse scored item* **Open ended:** Qualitative responses will be reported separately.
Secondary – (1) **confidence** communicating online about suicide	This outcome is measured using the Purpose designed #chatsafe online safety questionnaire (COSQ) with three questions on confidence when communicating online about suicide total score across all three vignettes.	Measured at Baseline (T1), Post-intervention (T2) and Follow Up (T3). **Primary endpoint:** Post-intervention (T2)	**Total score - COSQ_confidence:** Vignette 1 confidence score+ Vignette 2 confidence score + Vignette 3 confidence score
Secondary – (2) **willingness to intervene** against suicide online	**Willingness to intervene against suicide** (WIAS) measure contains two domains: Perceived Behavioural Control (PBC) and Intent to intervene (Intent).	Measured at Baseline (T1), Post-intervention (T2) and Follow Up (T3).	**WIAS_PBC:** Total score items 1 – 20 **WIAS_Intent:** Total score items 1 – 22

		Primary endpoint: Post-intervention (T2)	
Secondary – (3) perceived **internet self-efficacy**	**Perceived internet self-efficacy** (ISS) contains 5 domains: reactive/generative, differentiation, organization, communication, and search self-efficacy.	Measured at Baseline (T1), Post-intervention (T2) and Follow Up (T3). **Primary endpoint:** Post-intervention (T2)	**ISS_Reactive**: Total score of items 8, 9, 18, 19, 21, 23 **ISS_Differentiation**: Total score of items 4, 5, 6, 7 **ISS_Organization**: Total score of items 13, 14, 15 **ISS_ Communication**: Total score of items 17, 20 **ISS_Search**: Total score of items 1, 2
Secondary – (4) Intervention **safety** (**weekly content)**	Safety is measured using three items regarding to what extent did participants find each piece of weekly content distressing (or not), measured on a 3-point Likert scale (3 = very, 1 = somewhat, 0 = not at all).	Measured weekly throughout the intervention (Weeks 2 – 9).	**Weekly content safety** **Wk1_Safety:** Total score 1a_+ 2a_+ 3a **Wk2_Safety:** Total score 1a_+ 2a_+ 3a **Wk3_Safety:** Total score 1a_+ 2a_+ 3a **Wk4_Safety:** Total score 1a_+ 2a_+ 3a **Wk5_Safety:** Total score 1a_+ 2a_+ 3a **Wk6_Safety:** Total score 1a_+ 2a_+ 3a **Wk7_Safety:** Total score 1a_+ 2a_+ 3a **Wk8_Safety:** Total score 1a_+ 2a_+ 3a **Open ended:** Qualitative responses will be reported separately.
Secondary – (5) Intervention **acceptability**	Acceptability of the #chatsafe intervention as a whole (i.e., did participants find the content helpful and did it have any negative effects on them generally)	Post-intervention (T2)	**Acceptability** of the intervention **T2_Helpful:** Total score Item 1 (*How helpful did you find the campaign?)* **T2_NegEffects:** Total score Item 10 *(Did the campaign have any negative effects on you?)* **Open ended:** Qualitative responses will be reported separately.
Secondary – (6) Intervention **safety (as whole)**	Safety of the whole intervention as determined through number of (or absence of) adverse events throughout the trial (implementation risks).	Post-intervention (T2) and Follow-up (T3)	**Safety** of the intervention Total number of adverse events requiring follow up – "Adverse_Events_FUp"

			Total number of withdrawals, citing safety as primary cause: "Withdraw_Safety" Total number of responses indicating campaign resulted in feelings of suicide or self-harm: Total score Item 11 (*At any point during this study, did the campaign content you viewed as part of this study, cause you to feel suicidal, unsafe or cause you to experience the urge to self-harm?*) **Open ended:** Qualitative responses will be reported separately.
Secondary – (7) Intervention **feasibility**	Feasibility of the delivering the intervention as determined through number of participants recruited into the study, rates of study retention, and adherence to the intervention.	Post-intervention (T2)	**Feasibility** of the intervention **Recruitment:** # of participants reached and # converted into participants **Retention:** # of participants that completed T1 and T2 **Adherence:** % of responses to weekly survey (Depending on distribution, this will be reported in tertiles)
Secondary – (8) self-reported evaluations of the acceptability of receiving the intervention	Self-reported/open-ended questions asked of participants to measure their perceptions of receiving the intervention.	Post-intervention (T2)	**Open ended:** Qualitative responses will be analysed and reported separately.
Exploratory – (1) **subgroup differences** in the impact of the #chatsafe intervention	Subgroup differences: gender, age, previous exposure to suicide and self-harm, previous experiences of self-harm, level of social media usage, treatment adherence.	Post-intervention (T2)	**Gender:** Male / Female / Other **Age**: By year (depending on distribution, this will be split into two groups younger [16 – 20 years] and older [21 – 25 years]). **Lifetime "self_harm"**: Yes/No **Lifetime "suicide_ideation"**: Yes/No **Lifetime "suicide_attempt"**: Yes/No **Lifetime "suicide_bereavement":** Yes/No **Social media usage**: Depending on distribution, this will be reported in tertiles. **Treatment adherence**: Depending on distribution, this will be reported in tertiles (low, medium, high).
***Exploratory** – (2) safety, acceptability*	Self-reported open-ended evaluations of the safety, feasibility,	Post-intervention (T2)	**Open ended:** Qualitative responses will be analysed and reported separately.

*and feasibility of using social media for the purpose of sexual health promotion for young people**	and acceptability of receiving the PROSPECT intervention in the control group.		
Other variables **–** *(1) Self-harm and suicide history*	**Self-harm and suicide history**	Measured at Baseline (T1),	**Lifetime "self_harm"**: Yes/No **Lifetime "suicide_ideation"**: Yes/No **Lifetime "suicide_attempt"**: Yes/No **Lifetime "suicide_bereavement":** Yes/No
Other variables **–** *(2) Internet Use*	**Internet Use**	Measured at Baseline (T1), Post-intervention (T2) and Follow Up (T3).	**SM_Usage**: Depending on distribution, this will be reported in tertiles of social media usage (low, medium, high).

Outcomes were measured for both intervention and control group. Control group results of safety, acceptability and feasibility is part of a separate study that will not be reported in this protocol.

Descriptive analysis

State of residence, postcode, age, Aboriginal or Torres Strait Island status, gender identity, sexual orientation, primary language spoken at home, cultural background, and educational and occupational background, all at baseline, will be reported using descriptive statistics and will be checked for imbalance between trial arms, see Table 2.

Primary, secondary and exploratory analysis

Analyses will be performed on an intention-to-treat basis, where all individuals randomised will be included in the analysis by their allocated trial arm status regardless of whether they received all, part, or none of the intended treatments.

In the primary analysis, we will use linear regression to estimate the mean difference between the intervention and control arms in the change in the primary outcome between T1 and T2. The analysis will adjust for T1 outcome scores as a covariate and multiple imputation will be used to adjust for attrition bias (see below). . We will conduct 2 sensitivity analyses. One sensitivity analysis will be undertaken using complete cases only (i.e., repeating the primary analysis but only analysing participants who have complete T1 and T2 data). The second sensitivity analysis will include the following potential moderating factors as covariates: gender (male, female, other), age group (ie., 16-20 and 21-25 years), time spent on social media, and previous experience of suicide and self-harm. Multiple imputations will be used for all analyses to address attrition bias, with 50 imputation samples generated using chained equations. The variables used in imputation models are outlined in Table 3. Results will be reported in the summary table as illustrated in Table 4.

The analytic and reporting strategy described above will be repeated for all secondary outcome variables. Acceptability, feasibility and safety measures will only be reported for the #chatsafe intervention using descriptive tables and plots.

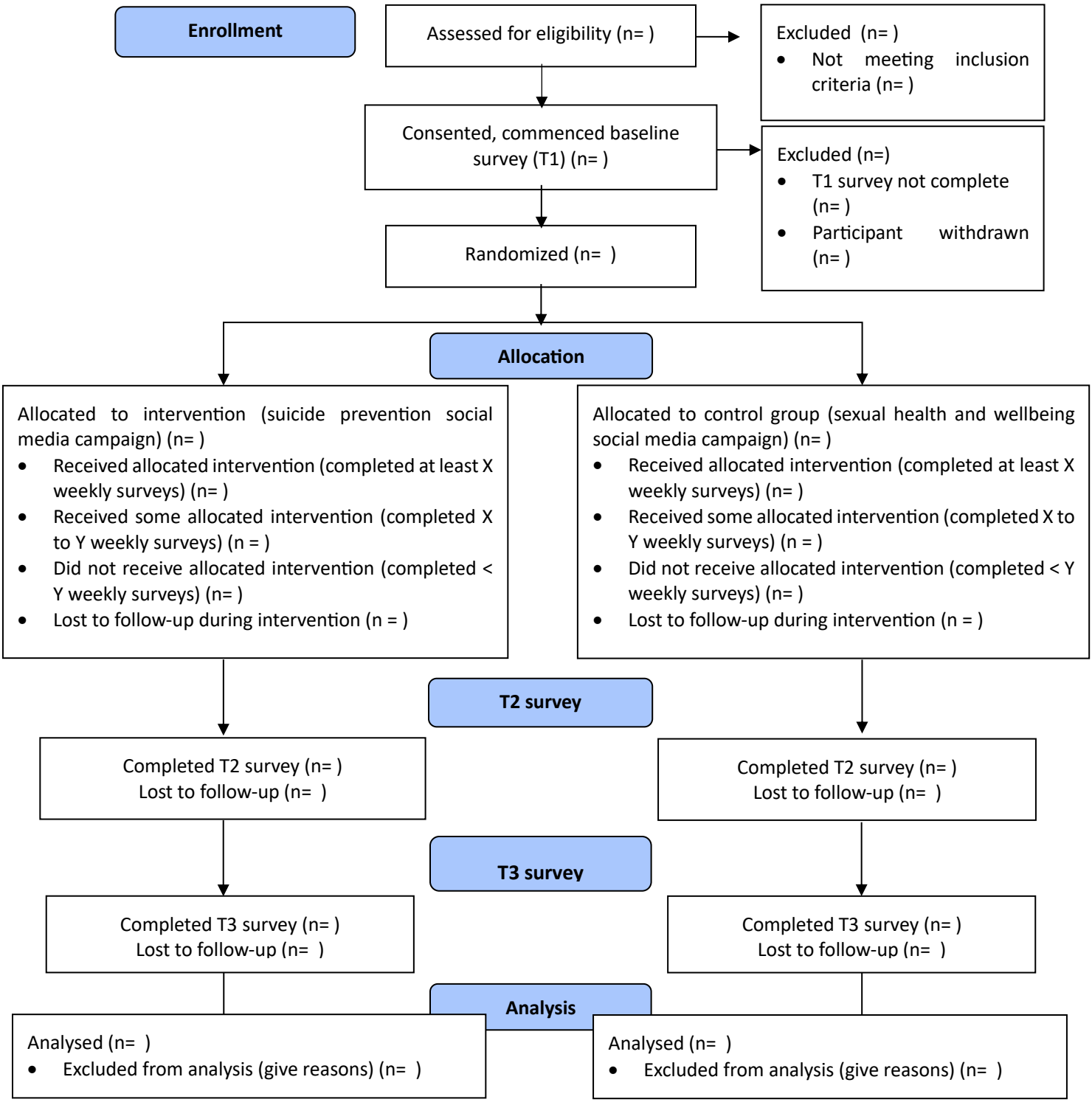

Figure 1. Trial profile. **Notes:** Lost to follow up reasons at all time points were: I found the study distressing/it made me feel suicidal; I thought the study was unsafe; I found the study boring/annoying; I found the study too time consuming; No reason, I just did not want to participate anymore; Other (free-text responses included not having the time anymore or moving overseas).

Table 2. Baseline characteristics of participants according to trial arm

	Intervention arm (n=)	**Control arm (n=)**
Age group, n (%)		
16 – 20 years		
21 – 25 years		
Australian state or territory of residence , n (%)		
Australian Capital Territory		
New South Wales		
Northern Territory		
Queensland		
South Australia		
Tasmania		
Western Australia		
Victoria		
Socioeconomic status (SES), n (%) [1]		
Low		
Middle		
High		
Gender identity, n (%) [2]		
Man or Male		
Woman or Female		
Non-binary		
Gender fluid		
I use a different term (examples include ___)		
Prefer not to answer		
Identifying as transgender or gender diverse, n (%)		
Yes		
No		
Unsure/questioning		
Prefer not to disclose		
Sex recorded at birth, n (%)		
Male		
Female		
Another term (examples include ___)		
Prefer not to disclose		
Sexuality , n (%)		
Heterosexual/straight		
Lesbian		
Gay		
Bisexual		
Pansexual		
Queer		
Questioning (not sure)		
Not listed (examples include ___)		
Prefer not to disclose		
Main language spoken at home , n (%)		
English		
Other (examples include ___)		
Cultural or ethnic group most identified with [3]		

	(open ended)
Aboriginal and/or Torres Strait Islander identity	
	No
	Yes, Aboriginal
	Yes, Torres Strait Islander
	Both Aboriginal and Torres Strait Islander
Currently studying	
	Yes
	No
Highest level of education	
	Year 7-8
	Year 9-10
	Year 11-12
	Some university
	Some TAFE
	Completed bachelor's degree
	Other (examples include ___)
Current employment status	
	Employed
	Unemployed – Full time student
	Unemployed
	Unable to work
	Other (examples include ____)
#chatsafe Online Safety Questionnaire	
	(COSQ_safety), mean (SD)
	(COSQ_confidence), mean (SD)
Willingness to Intervene	
	Perceived Behavioural Control, mean (SD)
	Intent, mean (SD)
Internet Self Efficacy	
	Reactive, mean (SD)
	Differentiation, mean (SD)
	Organization, mean (SD)
	Communication, mean (SD)
	Search, mean (SD)
Social Media Usage	
	Low
	Medium
	High

Note: [1] SES will be determined using participant postcode based on 2021 ABS Socio-Economic Indexes for Areas (SEIFA) Index of Relative Socio-economic Advantage and Disadvantage (IRSAD). [2] Participants were able to select multiple responses. [3] Some participants may have provided more than one response, and some did not respond.

Table 3. List of imputation variables for primary analysis

Measure	Time point	Variables
#chatsafe Online Safety Questionnaire (COSQ)- Safety	T1, T2 & T3	COSQ_Safety_Sharing, COSQ_Safety_Responding, COSQ_Safety_BereavedComms, COSQ_Safety.
#chatsafe Online Safety Questionnaire (COSQ)- Confidence (secondary outcome)	T1, T2 & T3	COSQ_confidence
Willingness to Intervene Against Suicide Questionnaire (WISQ)	T1, T2 & T3	WIAS_PBC, WIAS_Intent
Perceived internet self-efficacy (ISS)	T1, T2 & T3	ISS_Reactive, ISS_Differentiation, ISS_Organization, ISS_ Communication, ISS_Search
Auxiliary variables		
Age	T1	Age in years
Gender identity	T1	Gender identity categories (may combine category to account for low prevalence)
Sexuality	T1	Sexuality identity categories (may combine category to account for low prevalence)
Culturally and linguistically diverse	T1	Binary variable based on main language spoke at home and cultural or ethnic group identified
Not in Education, Employment, or Training (NEET)	T1	Combined based on current education and employment status.
Exposure to, and personal experiences of, suicide and self-harm	T1, T2 & T3	Lifetime self_harm; suicide_ideation, suicide_attempt, suicide_bereavement
Time spent on social media	T1, T2, T3	SM_Usage

Note: across all scales, if there are significant inconsistency in missing data across individual items, individual items will also be included in the missing data equation.

Table 4. Reporting primary and secondary outcomes for the primary endpoint

	Total sample (n =)	
Outcome at T2		
Intervention arm, n		
Control arm, n		
Mean change from T1 to T2		
Intervention arm, mean (SD)		
Control arm, mean (SD)		
Mean difference, Coef. (95% CI)		
Primary analysis	Coef (95% CI)	p-value
Effect size	SMD (95% CI)	
Sensitivity analysis (complete case)	Coef (95% CI)	p-value
Sensitivity analysis (confounder adjusted)	Coef (95% CI)	p-value

Notes: SD = Standard deviation; Coef. = Estimated coefficient; CI = Confidence interval.