

Evaluating a sexual violence primary prevention program at an Australian University: A realist protocol comprising a cluster non-randomized controlled trial and realist interviews

Innocent Mwatsiya

i.mwatsiya@latrobe.edu.au

La Trobe University

Jessica Ison

La Trobe University

Kerryn O'Rourke

Charles Darwin University

Kirsty Forsdike

La Trobe University

Sarah Vrankovich

La Trobe University

Jacqueline Kuruppu

La Trobe University

Freda Haylett

La Trobe University

Jacqui Theobald

La Trobe University

Gabriel Caluzzi

La Trobe University

Xia Li

La Trobe University

Adam Bourne

La Trobe University

Nicola Henry

RMIT University

Felicity Young

La Trobe University

Leesa Hooker

Study protocol

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Abstract

Background: Sexual violence is highly prevalent in university settings, yet there remains limited evidence on what prevention interventions work, for whom, and under what conditions. This article outlines the protocol for a mixed method realist evaluation of an Australian sexual violence prevention program for university students.

Methods/design: This study is designed to test and refine eight initial program theories developed with key informants. Four theories hypothesise changes in participant sexual violence knowledge, attitudes and behaviours. Outcomes of these will be tested in a two-arm parallel cluster non-randomized controlled trial. Realist interviews with program participants, university staff and facilitators will also test these outcomes, as well as their hypothesised mechanisms and contexts. Three initial program theories about implementation will be tested in the realist interviews only complemented with the Reach, Effectiveness, Adoption, Implementation, and Maintenance (REAIM) framework.

Study arms: The trial will be conducted with university students and staff across nine residential colleges at one Australian university in 2026. The residential colleges will be the unit of selection for assignment into clusters. Nine clusters will be allocated to either intervention (n=5) or control arms (n=4). Total student sample size n=191. The intervention group will receive the Consent and Relationship Education (CaRE) program, a 4-session group-based intervention that aims to educate participants on healthy relationships and the prevention of sexual violence.

Primary outcome: sexual violence knowledge. **Secondary outcomes:** sexual violence attitudes, behaviours (perpetration and victimization). Students in all clusters will complete surveys at baseline, immediate-post, 3-months-post and 6-months-post the intervention.

Discussion: To our knowledge, this study will comprise the first published trial and the first realist evaluation of a sexual violence primary prevention program delivered in an Australian university context. The use of realist methodology and mixed methods will advance the field's understanding of not only "what works" to prevent sexual violence, but also how, when and for whom it works (or not).

Ethics and trial registration: This study has been approved by the La Trobe University Human Research Ethics Committee (approval number HEC25176). The trial has also been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12625000602426p).

Background

The high prevalence of sexual violence in universities is well documented both in Australia and internationally. In Australia, the 2021 National Student Safety Survey showed that approximately 16% (or 1 in 6) of students reported experiencing sexual harassment in a university setting, while approximately 5% (or 1 in 20) of students reported experiencing sexual assault (Heywood et al., 2022). These rates are consistent with international data which show high prevalence of sexual violence and harassment

among university students, relative to the general population (Allroggen et al., 2016; Cantor et al., 2020; Anderson et al., 2021; Krahé et al., 2021). University campuses remain one of the highest-risk settings for students to experience sexual violence and harassment (Jones, 2025). For cisgender women and transgender and gender-diverse students, sexual violence and harassment rates are reported as even higher (Fedina et al., 2024; Hayes et al., 2025).

There has been a recent groundswell of student activism in Australia in response to this issue. Campaigns such as End Rape on Campus, The STOP Campaign, and Fair Agenda have long demanded that universities address the issue of sexual violence on campus. From 2026, a National Higher Education Code to Prevent and Respond to Gender-based Violence (GBV) will require higher education providers registered with the Tertiary Education Quality and Standards Agency, to proactively work to prevent and respond to GBV (National Higher Education Code to Prevent and Respond to Gender-based Violence 2025). However, despite such policy advancements, there is a dearth of good quality evidence about what kinds of programs make a difference in the university context (Coker & Ray, 2024; Kettrey et al., 2023). This is not a criticism of practitioners and organisations, who typically implement interventions in resource-strained contexts. Rather, the evidence gap reflects longstanding poor investment in primary prevention and its evaluation. (Mitra et al., 2022; Portillo-Castro, 2016; Seixas et al., 2021; Sheppard et al., 2024; Sheppard et al., 2025).

Most university prevention interventions (such as Real Consent and Green Dot) are from the United States of America (USA), are secondary prevention focused rather than primary prevention, and target men as bystanders of other men's violence and not as people potentially using violence themselves (Hooker et al., 2020). Additionally, much of the evidence is from quantitative studies that do not explain how, when and for whom interventions work. Producing explanatory evidence can be resource-intensive but we argue that the long-term costs of neglecting to generate this evidence are likely to be even greater (Mayhew, 2003; Sheppard et al., 2024). Without such evaluation, programs may continue to rely on dominant intervention approaches such as education programs without understanding how, when and for whom they work (and do not work).

Existing literature shows that a significant number of sexual violence prevention interventions are offered as one-off, short, online self-directed sessions (Acquaviva et al., 2023; Anderson & Whiston, 2005; McQueen et al.). In university settings, the widespread adoption of these formats reflects institutional contexts characterised by the low prioritisation of sexual violence prevention (Henry, 2024; Perkins & Warner, 2017; Sall, 2020). As institutions, universities have a history of adopting reactive attitudes towards sexual violence, including treating it as a reputational threat and pursuing containment, instead of justice, or aiming to prevent it from occurring in the first place (Marques et al., 2020; Osuna, 2023; Shannon & Bull, 2024; Sulkowski, 2011). The capitalist, neoliberal, profit-driven environments within which tertiary education is delivered in Australia (and elsewhere) incentivizes universities to act in this way (Colpitts, 2022; Hurtado, 2021; Slaughter & Rhoades, 2000). Meaningfully addressing sexual violence would require a genuine acknowledgment of the pervasive culture and high prevalence of sexual violence in university settings, an admission that risks damaging institutional

reputation and potentially deterring student enrolments, with direct financial consequences. While the literature documents the institutional contexts of universities, there has been limited examination of how such contexts shape the mechanisms through which prevention programs operate, and for whom these approaches are likely to be effective. This study advances the literature by examining how organisational priorities, institutional risk management, and resource allocation function as contextual conditions that enable or constrain mechanism activation within sexual violence prevention programs in university settings.

In addition to institutional reluctance to address sexual violence, there are also pragmatic considerations that may limit the reach and effectiveness of prevention programs in universities. Existing studies have identified time constraints and workload pressures as salient barriers within university settings. Students and staff often have busy schedules which leave very little room for attending in-person multi session programs (Bonar et al., 2022; Garcia et al., 2012; Graham et al., 2021; Mitra et al., 2022). These limitations can also be linked to institutional reluctance because, while most universities state they prioritize safety and often reflect this through their policies, few universities are willing to make practical accommodations to enable participation in prevention programs (Humphreys & Towl, 2021). Such accommodations would include offering protected time, resourcing programs sufficiently, or offering meaningful incentives for students and staff to participate. The increased casualization of the university workforce in Australia (Woelert et al., 2025) is also a major barrier to staff training if staff are not paid to attend. These constraints represent a contextual feature of university settings that is likely to affect program reach and engagement. In such contexts, mechanisms related to motivation, perceived relevance, and opportunity to participate may be inhibited. However, existing studies rarely examine how these conditions interact with program implementation to produce different outcomes across settings. This study addresses that gap by explicitly analysing how institutional and logistical contexts influence these mechanisms and their downstream outcomes.

These cultural and logistical barriers to participation for students and staff impact both the reach and effectiveness of prevention programs. Program effectiveness is an important consideration for sexual violence prevention efforts in university settings. Ineffective intervention approaches can cause inadvertent harms, by reinforcing damaging stereotypes, failing to anticipate and prepare for backlash (overt hostility or more subtle forms of resistance) or failing to engage critically with the social conditions that sustain a culture of sexual violence (DeGue et al., 2014; Levin, 2016; Malamuth et al., 2018). The potential for harm is particularly heightened in closed settings such as university residences. In these settings, backlash may increase the risk of sexual violence and harassment. When prevention efforts are poorly designed and fail to anticipate, and respond to backlash, they may inadvertently increase risk for students and staff on campus and in residences. In realist terms, these harms suggest the activation of unintended mechanisms within the context of university residences. While the literature identifies these risks, there has been limited investigation into the contextual conditions under which backlash is more likely to occur and how programs can mitigate these effects; an issue this study will examine directly.

This article outlines the protocol for a study that aims to develop explanatory evidence of how, when and for whom a primary prevention sexual violence program works in an Australian university residential setting. Below, we will explore the methodology.

Realist evaluation methodology

Realist evaluation methodology and the mixed methods approach have been chosen for their ability to not only find out “what works”, but how, when and for whom it works (Pawson & Tilley 1997). This is important because even if a program is found to be effective, it is never effective for everyone and everywhere, so understanding how and why differential outcomes occur is critical for making refinements to, sustaining and/or scaling a program. Realist evaluation is a theory-driven methodology designed to open the ‘black box’ of a program – determining how, when, and for whom it works (and does not work) (Pawson & Tilley, 1997). Realist evaluation methodology follows a cycle of inquiry (Marchal et al., 2012; Pawson & Tilley, 1997). For this study, the cycle started with the gleaning and development of hypothesised program theories, structured as the following Context-Mechanism-Outcome (CMO) configurations, to be tested via this protocol.

Realist program theories

The realist evaluation is designed to test and refine eight initial program theories co-developed with key informants of the program.

The first four theories are about the causal processes through which participants are expected to learn and develop prosocial knowledge, attitudes and behaviours that prevent sexual violence.

CMO 1: Assertive communication

For students who struggle with assertive communication, particularly in situations involving sexual violence or harassment (*context*), the program will provide practical communication strategies and model examples of boundary-setting (*mechanism: resource*), which will help students recognise their right to express their needs and increase their confidence to communicate clearly in uncomfortable or unsafe situations (*mechanism: reasoning*), resulting in improved ability to assert boundaries, resist coercion and seek assistance when at risk (*outcome*).

CMO 2: Power and Intersectionality

When students rely on gender norms that inhibit respectful and reciprocal communication around consent (*context*), the program will challenge and reframe their understanding of social and sexual norms (*mechanism: resource*), enabling them to critically reflect on and question the norms they uphold

(*mechanism: reasoning*). This will lead to increased willingness and ability to engage in respectful consent communication, with reduced endorsement of harmful gender norms (*outcome*).

CMO 3: Consent

University students have diverse and not always accurate understandings of consent and their legal responsibilities (*context*). The program will challenge commonly held social norms and encourage participants to learn and reframe how they think. In response, participants will be open to new knowledge about the drivers of sexual harm including alcohol and pornography, and consent laws (*mechanism*), which will result in improved ability to negotiate consent (*outcome 1*) and reduced perpetration of sexual violence (*outcome 2*).

CMO 4: Bystanders

When university students witness sexual violence or harassment but feel unsure about how to intervene (*context*), the program will instil a sense of responsibility by helping participants recognise their role and the opportunities available to intervene (*mechanism: reasoning*). Learning about prosocial behaviours will also activate empathy and support students to better understand the experiences of others (*mechanism: reasoning*), resulting in increased confidence to intervene as bystanders, including use of bystander skills in everyday life (*outcome 1*), and reduced tolerance for sexual violence and harassment (*outcome 2*).

The remaining four theories are about program implementation.

CMO 5: Collective active learning and role playing

The program will use interactive and relatable teaching methods such as discussions, role-plays and group work, delivered within a supportive peer environment (*context*). This will engage students in active learning and co-creation of materials (*mechanism: resource*), fostering a sense of ownership, responsibility and commitment to prevention efforts (*mechanism: reasoning*). As a result, participants will develop a collective commitment to preventing sexual violence on campus (*outcome 1*). In addition, by fostering open dialogue and creative collaboration on sexual violence prevention (*mechanism: resource and reasoning*), the training will be perceived as more relevant and applicable, leading to better retention of skills and greater confidence in using them (*outcome 2*).

CMO 6: Facilitator skills

The program will be co-facilitated by two facilitators with different backgrounds, genders and varying levels of experience in sexual violence prevention (*context*). This will create a diverse learning environment for participants (*mechanism: resource*), enabling them to discuss sensitive issues without fear of stigma or retaliation (*mechanism: reasoning*). As a result, participants will feel respected and

safer and will engage in positive and constructive interactions with one another (*outcome 1*). This approach will also support effective delivery of the program, with sessions that are both engaging and informative (*outcome 2*).

CMO 7: Institutional buy-in

The university operates under an existing action plan with only a limited focus on sexual violence prevention but demonstrates institutional commitment to addressing sexual violence (*context*). The program will leverage this commitment to secure sustained attention to sexual violence prevention and resource allocation for sexual violence prevention (*mechanism: resource*), enabling staff and facilitators to deliver the program effectively (*outcome*).

CMO 8: Timing of the sessions

For students who are busy and may not have time to attend programs that clash with their academic schedule (*context*), the program will deliver sessions outside of standard business hours (*mechanism: resource*), which will make students feel that their time is respected and valued (*mechanism: reasoning*). This will lead to high levels of participant engagement and satisfaction with the sessions (*outcome*).

Realist methodology does not prescribe data collection methods. These are theory-led, refined theories that provide plausible explanations for how, when, and for whom the program works (and does not) (Pawson & Tilley, 1997). However quantitative methods are considered useful for examining (observable) outcomes and contexts, and qualitative methods for (unobservable) mechanisms and contexts. As such, below, we look at the methods.

Methods

The study comprises a cluster non-randomized controlled trial and qualitative realist interviews with program participants, facilitators and university staff.

The trial

The trial is a two-arm parallel cluster non-randomized controlled trial, designed to test hypothesised program outcomes. It will be conducted with university students across nine residential colleges at one Australian university during 2026. The university operates across multiple campuses in regional and urban areas in Australia. The residential colleges at the university will be the unit of selection for assignment into clusters. Clusters will be allocated to either the intervention (IG) or control group (CG) as illustrated in table 1 below.

Table 1
Cluster allocation

Campus	State Region	Residences	# students on campus	Trial Arm
A	North	A1	120	CG
		A2	172	CG
		A3	73	CG
B	South	B1	440	CG
		B2	240	IG
C	South	C1	100	IG
		C2	47	IG
		C3	149	IG
D	Northwest	D1	87	IG

The trial is designed as a non-randomized trial for several reasons. In part, the clusters (residential colleges) at the university are not easily separable into comparable units for random assignment because geographically and administratively most residential colleges overlap. In addition, the university also expressed a preference for particular colleges to receive the intervention due to higher perceived need. As a result of these considerations and the practical and ethical implications for doing randomization in this context, we opted for a purposive allocation strategy rather than full randomization. In this study, the intervention arm will receive a 4-session group-based educational intervention called the Consent and Relationship Education (CaRE) program, which we will detail below. The intervention arm will be compared with a waitlist control group who will only receive the intervention after the study.

Figure 1 below provides the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram, as a summary of the design of the study.

The CaRE intervention

The intervention group will receive the CaRE program. CaRE is a group-based intervention that aims to educate participants on healthy relationships and the prevention of sexual violence by improving participants' sexual violence knowledge, attitudes and behaviours. CaRE is developed and delivered in collaboration with a well-established statewide, community-based specialist sexual violence service with experience in running prevention programs. For the university setting, the CaRE program has been adapted for young adults, their lifestyle and risk factors, and cultural dynamics, so contains sensitive and potentially triggering content.

The table below provides a summary of the core sessions of the CaRE intervention:

Table 2
CaRE sessions

Session Content	Session Order
Rights and Responsibilities	1
Power and Social Norms	2
Prosocial Behaviours	3
From Message to Movement: Practicing Consenting Conversations	4

Standard curriculum

Both the intervention and control groups will be offered the standard educational curricula, which includes:

- A 45-minute non-compulsory, online module called Consent Matters offered to all university students.
- Media campaigns, including digital and physical resources such as posters around campus. The campaigns centre messages such as 'Sexual Harm is not OK' with links for students to access the university's Student Safety and Wellbeing team website.
- Student leaders are offered the chance to sign up for staff training, including training on trauma-informed practice and bystander intervention.
- All students have access to the university's Student Safety and Wellbeing team, who offer free counselling as well as case management for assistance with reporting of sexual violence and harassment experiences (details provided in the *Unistart* student online academic orientation module).

Data collection methods

Survey data

Eligibility criteria for survey

Eligibility criteria are based on the program participant cohort. Inclusion criteria are:

- Students aged between 18 and 35 years
- Students living in university campus accommodation during 2026

Survey recruitment

All students eligible for the survey will be invited via official email from their university. The email will include a Participant Information and Consent Form (PICF) and link to an online REDCap (Harris et al., 2019) survey to capture consent and survey responses from respondents. The PICF will explain the purpose of the study, what participation involves, possible risks and benefits associated with participation, and participants' rights, including their right to withdraw from the study at any time. Consent will be given electronically by ticking a box before participants can access the survey.

Realist interviews

Qualitative realist interviews will be conducted to test hypothesised participant outcomes (triangulating with trial data) and their contexts and mechanisms (CMOs 1 to 4), as well as implementation theories (CMOs 5 to 8). Initial program theories will be presented to participants as provisional explanations and iteratively refined through participants' accounts, in line with the realist teacher–learner cycle (Pawson & Tilley 1997; Manzano 2016).

We will conduct the following interviews:

- Individual interviews with up to 20 students residing on campus;
- Individual interviews with up to 10 staff employed at the partner implementing organization and
- Individual interviews with up to 10 university staff where the program will be implemented.
- Two focus groups with a total of 20 students (10 students/group) from our intervention arm. The control arm is excluded from the qualitative research, as the aim is to explore process and impact outcomes specific to the program.

Sampling

Survey sample size estimates

Based on the most recent meta-analysis of sexual violence prevention programs (Kettrey et al., 2023), knowledge of sexual assault was associated with a Hedges' g of 1.07 (95% CI [0.25, 1.89]). Given the wide confidence interval, which indicates substantial uncertainty and the possibility of a much smaller true effect, we opted to use a more conservative estimate ($g = 0.6$) for planning purposes, which corresponds to a standardized mean difference (SMD) of 0.6.

The sample size calculation is based on a one-sided t -test, with degrees of freedom determined by the total number of subjects and a Type I error (α) of 0.025. Assumptions include a common subject-to-subject standard deviation of 1, an intra-cluster correlation coefficient of 0.026 (Lee & Wong, 2020), and

a coefficient of variation for cluster sizes of 0.76 (calculated from the overall population size across clusters). A total of 144 participants (80 for intervention group, 64 for control group), across nine clusters (5 clusters for IG, 4 clusters for CG) will be recruited for both intervention and control groups. Calculations were performed using PASS 2025 (version 25.0.2). The number of participants recruited from each cluster will vary according to cluster population size, ensuring proportional representation while maintaining the overall target sample size. In cases where the number of participants for each cluster is not a whole number, it will be rounded up to the nearest greater integer. To allow for an anticipated dropout rate of approximately 20% in each cluster, the total sample size will be increased to 191 students- 107 in the intervention group and 84 in the control group.

Realist interviews sampling

As we alluded to above, sampling for realist interviewing is theory-based (Pawson, 1996; Pawson & Tilley, 1997). Program participants and program facilitators will be interviewed for their high “CMO investigation potential” (Greenhalgh et al., 2017, p. 2). A maximum variety sample will be sought to provide sufficient variation to test and refine explanations for differential outcomes in our program theories. Other sampling criteria are based on practical and ethical considerations as follows:

- Students who have completed at least one CaRE session.
- Students who are available and consent to the interviews and focus groups.
- Program facilitators and university staff who are involved in the program as part of their professional roles

Interview recruitment

Interview participants will be invited via email from their university and via residence social media platforms, residence in-person events and student leadership networks. Consent forms will be sent and received back via email. As an incentive, students who participate in all surveys will be sent \$20 vouchers at the end of the study to show appreciation for their contributions. Students who participate in interviews will be given an additional \$20 voucher to show appreciation for their participation.

Outcomes

The trial will measure the following outcomes: sexual violence knowledge, attitudes, and behaviour outcomes reported by program participants.

Primary outcome

The primary outcome for this trial will be university student's *knowledge related to sexual violence*. For all outcomes, outcome assessors and data analysts will remain blinded to group allocation during statistical analysis of the de-identified survey data.

Key secondary outcomes

Secondary outcome measures include student *attitudes* related to sexual violence, *sexual violence victimization*, and *sexual violence perpetration* by students.

Outcome measures

Knowledge related sexual violence

To assess changes in student knowledge, we will use the Recognize Violence Against Women (RVAW) scale; a validated subscale of the Understanding Violence Against Women scale in the Australian National Community Attitudes towards Violence Against Women Survey (NCAS) (Coumarelos et al., 2023). The NCAS is a nationally representative survey conducted in Australia to measure changes in knowledge, attitudes and beliefs about violence against women.

The RVAW measures respondents' knowledge of violence against women (including sexual violence and harassment) using four questions on a 5-point Likert scale with responses ranging from 1 = Yes always, 2 = Yes usually, 3 = Unsure, 4 = Yes sometimes and 5 = No. Questions include items such as, "*do you consider abusive messages or comments targeted at women on social media to be a form of violence against women?*". By capturing changes in these forms of knowledge, we will capture changes in knowledge items that are linked to drivers of sexual violence.

Attitudes related to sexual violence

The Objectifying Women and Disregarding Consent (OWDCS) scale will be used to measure changes in students' sexual violence attitudes. The OWDCS is also a validated subscale of the NCAS (Coumarelos et al., 2023). It measures changes in beliefs that objectify women and disregard the importance of consent. This scale has 15 items on a 5-point Likert scale (1 = Strongly disagree to 5 = Strongly agree). The OWDS scale will help detect changes in attitudes that underpin sexual violence. Example items include: "*If a woman is raped while drunk or affected by drugs, she is at least partly responsible*" and "*If a woman is drunk and starts having sex with a man, but then falls asleep, it is understandable if he continues having sex with her anyway*".

Sexual violence victimization

Measurement of victimization will be conducted using the Contact module of the Revised Sexual Experiences Survey Victimization Version (SES-V) (Koss et al., 2024). The SES-V is one of the most widely used tools for sexual violence victimization (Koss et al., 2024). The Contact module measures experiences of specific unwanted sexual behaviours involving physical contact. It has 11 items. With five response options within each item e.g., *option a = non-penetrative sexual contact, option b = oral penetration, option c = vaginal/genital opening penetration* etc. Example items from this scale include, *“Someone misused their position of authority over me to penetrate my vagina/genital opening”*. The SES-V's use of behaviour-specific language minimizes ambiguity, and this is desirable for our study.

Sexual violence perpetration

Perpetration of sexual violence will be measured using the Australian Institute of Criminology's Perpetration of Sexual Violence in a Community Sample of Adult Australians survey (PSV-A) (Doherty & Dowling, 2024). This survey has been used with an Australian sample which, we argue, gives it additional local relevance. It measures perpetration using behaviourally specific items. Example items include, *“Have you ever kissed someone when they didn't want you to?”* Behavioural-specific questions are key features of this scale and a good fit for our study.

Table 2

below summarizes the instruments and data collection points described above. A measurable change in sexual violence perpetration and victimization immediately post program is not expected, hence no data collection immediately post intervention.

Sexual Violence Outcome	Instrument	Data Collection Point			
		Baseline	Post	3 months	6 months
Knowledge	RVAW (Coumarelos et al., 2023)	x	x	x	x
Attitudes	OWDC (Coumarelos et al., 2023)	x	x	x	x
Victimization	SES-V (Koss et al., 2024)	x		x	x
Perpetration	PSV-A (Doherty & Dowling, 2024)	x		x	x

Table 3: Summary of outcome measurement

Implementation outcomes

Program implementation will be assessed using the RE-AIM framework (Holtrop et al., 2018) and the realist outcomes using the program theories outlined earlier. We consider these outcome streams to be complementary; where the trial outcomes will quantify what changed and the realist outcomes will provide explanatory depth, by clarifying how and under what institutional conditions these changes

occurred. Collectively, this structure provides a coherent analytical model that allows us to situate the statistical data within realist program theories in order to unpack the realities of program delivery and the contextual factors that produce change. RE-AIM findings will be interpreted through the realist program theories to examine how reach, adoption, and implementation interact with contextual conditions to enable or constrain mechanism activation.

Data analysis

Statistical hypotheses

The study will evaluate whether the identified primary and secondary outcomes in the intervention group differ to those in the control group.

Quantitative data/Statistical methods-analysis

The study results will be reported using the RAMESES realist evaluation reporting guidelines (Wong et al., 2016) and the Transparent Reporting of Evaluations with Non-randomized Designs (TREND) guidelines for non-randomized studies (Des Jarlais et al., 2004). The proportion of students completing baseline, immediate post, three and six-month follow-up surveys will be reported. A descriptive analysis will be used to summarize and describe the baseline characteristics (categorical or continuous variables) of the student participants, such as age, gender, sexual orientation, Indigeneity, country of birth and language spoken at home. Descriptive analyses, including means and standard deviations for the continuous primary and secondary outcome variables, will be reported at baseline, immediately post-intervention, and at follow-up.

The primary outcome is *sexual violence knowledge* measured by RVAW (Coumarelos et al., 2023) and as captured in CMOs 1 and 2 above. We will compare the change in participant pre-post program knowledge scores between the intervention and the control group. Scores will be compared in a linear mixed-effects model, incorporating a random intercept for cluster to account for the clustered design and intra-cluster correlation; a fixed effect for group allocation (intervention vs. control). Furthermore, the post-program score will be used as the outcome, with baseline score and additional covariates collected at both the student and cluster levels included in the model to explore their potential influence.

While confounders are assessed statistically to account for differences between groups, they are also understood in realist terms as *contextual features* that may influence how mechanisms operate in different settings and for different participants. We illustrate this in the table below. Some of these contextual features (e.g., gender identity) were not specified in the initial program theories but were identified during study design as likely to shape mechanism activation. Baseline knowledge is treated as a conditioning context for mechanism activation rather than as an outcome. Their inclusion enables us

to test and refine the program theories iteratively, examining how context influences mechanisms and outcomes across clusters.

This analysis will be repeated for secondary outcomes (e.g., victimization, attitudes and perpetration). Furthermore, for both primary and secondary outcomes, all four time points (baseline, immediate post-intervention, three-month, and six-month follow-up) will also be analysed using linear mixed-effects models that include fixed effects for group, time, and their interaction, as well as random intercepts for clusters and individuals. Baseline measures will also be included. An intention-to-treat analysis will be applied. For the primary outcome analysis, missing data will be assessed using Little's (1998) MCAR test. If non-significant, complete-case analysis will be used; if significant, multiple imputation will test robustness.

Table 3 below identifies the confounding and covariate variables in this study, as well as our control strategies for each of these variables. The group effect will be tested using a one-sided hypothesis test with a significance level of $\alpha = 0.025$, while all other tests will use a two-sided significance level of $\alpha = 0.05$.

Multiple secondary outcomes will be analysed without formal adjustment for multiplicity, as these outcomes are considered exploratory. The primary outcome is the focus of confirmatory hypothesis testing, while secondary outcomes provide supportive information. These unadjusted p-values will be reported and interpreted with appropriate caution.

Qualitative analysis

Interview data will be transcribed and uploaded into NVivo/MAXQDA (QSR International Pty Ltd, 2025; VERBI Software, 2022) for coding and analysis. Each initial program theory will be set up, with the theory title as a code, and each context, mechanism (resource and reasoning), and outcome as a sub-code. The transcripts will be coded deductively to the existing sub-codes (proving or disproving the hypotheses), and abductively to newly created sub-codes. Coding will proceed through iterative abductive and retroductive inference, with abduction used to imaginatively elaborate and re-describe emerging patterns (Jagosh, 2020; Meyer & Lunnay, 2013; Mukumbang et al., 2021), and retroduction used to infer the underlying causal mechanisms by reasoning back from observed outcomes to clarify how the program is generating the outcomes (Jagosh, 2020; Mukumbang et al., 2021).

Integration of both methods within the realist design

We expect that the evidence for mechanisms and outcomes will emerge from both the survey measures and the qualitative data from participant and staff interviews. As such, our Realist analysis will focus on developing a comprehensive understanding of the data that goes beyond effectiveness outcomes. For instance, if quantitative data show gains in sexual violence knowledge, Realist analysis will test whether

these shifts align with mechanisms such as clarification of consent laws or reframing of responsibility from victims to perpetrators. Similarly, if bystander confidence improves, we will assess whether this is linked to mechanisms of increased empathy and perceived responsibility as described in the program theory.

The integration of qualitative findings with the statistical analysis will be iterative. We will systematically compare quantitative patterns with qualitative accounts, revising the program theories where outcomes diverge from expectations. We will maintain a theory log to document these refinements, and we will produce a mechanism map to illustrate the relationships between CMOs across the program.

Table 4 lists the contextual features to be examined across both the quantitative and qualitative components of the study. In the trial, these features are treated statistically as confounders or covariates to account for differences between groups. Within the realist analysis, they are interpreted as contextual conditions that may influence the activation of mechanisms and the generation of outcomes. The table identifies each feature, its statistical and realist roles, the rationale for inclusion, and the analytic strategy to be used in both strands. The term ‘confounder’ is used here in its statistical sense and does not imply causal irrelevance within the realist analysis. Not all contextual features are expected to be equally salient across all CMOs; their relevance will be empirically examined during theory refinement.

PLACEHOLDER FOR TABLE 4. CONFOUNDERS/CONTEXTUAL FEATURES AND THEIR ROLES

Ethical considerations

This study has ethical approval, the details of which are provided in the Declarations below. To maintain ethical standards of care, each month, the Dean of each residential college or another member of staff will report any adverse events arising from the intervention to the Trial Management Committee. Any serious adverse events that might plausibly be caused by the intervention will be immediately reported to the governing Human Research Ethics Committee. All survey and qualitative data will be securely stored on the REDCap database (Harris et al., 2019) and the university’s secure research drive respectively.

Discussion

To our knowledge, this study is the first realist evaluation in Australia to embed a trial of a sexual violence prevention intervention in a university setting. By employing realist evaluation as a methodological framework and embedding a non-randomized trial within it, the study makes a substantive contribution to how sexual violence prevention can be evaluated in complex institutional environments such as universities. Particularly in the contemporary state of evaluative evidence where

descriptive evaluations are dominant (DeGue et al., 2014; Piolanti et al., 2022), this protocol demonstrates how outcome measurement can be integrated with realist explanation to provide deep and nuanced understanding for informing program refinement, sustainability and scalability, while strengthening methodological rigour and practice relevance.

A key contribution of this study is its explicit treatment of context as analytically central, rather than as a background variation that needs to be controlled. This orientation is particularly important in university settings, where residential colleges are socially dense and administratively layered, which often renders randomisation impractical and, in some cases, undesirable. Using a realist framework, we treat these institutional and social conditions as active features that shape how the program operates and for whom it is likely to be effective. Our purposive allocation of colleges into clusters mirrors real-world decision-making within universities and enables examination of how factors such as perceived need, institutional preferences, and organisational structures influence how program outcomes are generated and patterned.

Within this context-sensitive design, the embedded trial provides a structured means of measuring outcomes. Rather than functioning as a standalone test of effectiveness, the trial sits within the broader realist framework and quantitatively assesses outcomes that are explicitly theorised in the realist program theories. This alignment strengthens causal explanation by enabling observed outcome patterns to be interpreted and adjudicated against hypothesised mechanisms operating in particular contexts, using evidence from both the trial and the realist interviews, rather than relying on effect estimation alone. In doing so, the study advances a model of sexual violence prevention research that integrates experimental designs with realist explanation, in order to better understand how and why outcomes occur alongside whether change is observed.

Our selection of sexual violence knowledge as the primary outcome for this trial allows us to advance how the prevention literature understands sexual violence outcomes. Knowledge is central to several of the program's initial CMOs and is a plausible early outcome in the causal chain of prevention (Banyard et al., 2007), treated within the realist program theories as an intermediate outcome that conditions later changes in attitudes and behaviours rather than as an endpoint in itself. In terms of measurement, we argue that it is a construct that is relatively stable over short timeframes and less susceptible to spontaneous fluctuation. These attributes strengthen confidence that observed changes are less likely to reflect short-term fluctuation. The confidence is further bolstered by the use of validated, reliable instruments and the inclusion of baseline covariates which will allow us to align the trial's statistical modelling with realist understandings of baseline differences as contextual features rather than sources of bias alone.

This study also contributes to ongoing conversations about the evaluation of behavioural outcomes in sexual violence prevention. While behaviour change remains a longer-term ambition of the sexual violence prevention field, existing evidence suggests that detectable effects on perpetration and victimisation are typically small and require large samples (DeGue et al., 2014; Kettrey et al., 2023). By

prioritising knowledge as the primary outcome with attitudes and behavioural outcomes as secondary outcomes, the study adopts a pragmatic and theoretically coherent approach that reflects both the realities of prevention work and the limits of current evidence around the effect sizes linked with behavioural outcomes.

Taken together, this protocol offers a methodological template for future sexual violence prevention research in universities. It demonstrates how realist evaluation can be used as an overarching framework to integrate quantitative and qualitative data, accommodate program complexity, and generate theoretically transferable explanations about what tends to work, for whom, and under what conditions beyond a single setting. In a national context where rigorous evaluations of university-based prevention are scarce, this study provides both empirical insights and a model for how prevention research can be designed to better inform policy, practice, and institutional change.

Abbreviations

CaRE

Consent and Relationship Education

PIPS

Partners in Prevention of Sexual violence

Declarations

Ethics approval and consent to participate

This study has been approved by the La Trobe University Human Research Ethics Committee (approval number: HEC25176). The La Trobe University Human Research Ethics Committee is the trial sponsor and can be contacted via email at humanethics@latrobe.edu.au or over the phone on +61 3 9479 1443. The trial has also been registered with the Australia New Zealand Clinical Trials Registry (ACTRN12625000602426p).

All study participants will be asked to provide informed consent to participate in data collection.

All members of the research team have state issued Working with Children Checks (WWCC).

Consent for publication

Not applicable.

Trial status

The trial will commence in semester 2 of 2026. The results will be available by semester 2 of 2027.

Availability of data and materials

Not applicable

Declaration of interests

The authors declare that they have no competing interests.

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Authors' contributions

LH, JI, KF, FY, JT, GC, AB, & NH conceived of the trial and led the trial design, overall analysis plan (with lead support from IM), and the funding application. IM, JI, KO, LH, JK, FH, SV, KF, NH, AB, XL JT & GC drafted the manuscript. All authors contributed to refinement of the study protocol and read and approved the final manuscript.

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Table 4

Table 4. Confounders/Contextual features and their roles

Variable / Contextual feature	Type (statistical role / contextual role)	Rationale	Control / Analytic strategy
Campus location	Confounder / Contextual condition influencing mechanism activation: statistically treated as a confounder (associated with allocation and outcomes) but understood as a contextual feature shaping exposure, norms, and institutional cultures.	Some campuses elected to receive the intervention due to perceived need and may differ in baseline risk, culture, or readiness for prevention work. These campus-level contexts may influence both outcomes and how mechanisms are activated.	For the trial, campus location will be included as a covariate in regression models to adjust for baseline differences. For the realist analysis, differences across campuses will be interpreted as contextual conditions that may influence mechanisms, informing refinement of program theories.
Discipline of study	Confounder / Contextual feature shaping reasoning processes: statistically treated as a confounder but understood as a context influencing how content is interpreted	Different disciplines may be associated with varying social norms, peer cultures, and prior exposure to discussions of consent and power, shaping baseline attitudes and receptiveness to intervention messages.	Measure at baseline and include as a covariate if imbalanced. In realist analysis, disciplinary differences will be explored as contextual influences on how participants reason with and apply program content.
Age	Confounder / Developmental context: statistically treated as a confounder but understood as a contextual factor influencing life stage and social experience	Age may influence risk behaviors, relationship experience, and familiarity with consent discourse, which in turn may shape how mechanisms are triggered by the intervention.	Measure at baseline and include as a covariate. In realist interpretation, age-related differences will be examined as contextual factors affecting mechanism activation.
Gender identity	Confounder / Contextual condition influencing mechanism activation: statistically treated as a confounder but understood as a key contextual feature shaping engagement and outcomes	Risk, pre-existing knowledge, social positioning, and engagement with prevention messaging are gendered, potentially influencing both uptake of the intervention and outcomes.	For the trial, measure at baseline and include in quantitative models as a confounder. For realist analysis, observed gender differences will be examined as evidence of how gendered contexts shape mechanisms, using qualitative data to explore why and how these differences arise.

Domestic vs international student status	Confounder / Cultural and institutional context: statistically treated as a confounder but understood as a contextual feature shaping access and interpretation	International students may differ in prior education, cultural norms, language proficiency, and familiarity with Australian legal and institutional systems, all of which may affect engagement and outcomes.	Measure at baseline and adjust in quantitative analyses. In realist analysis, domestic/international status will be treated as a contextual condition shaping how mechanisms such as understanding and interpretation are activated.
Previous exposure to prevention education (including Unistart)	Confounder / Prior exposure context: statistically treated as a confounder but understood as a contextual feature influencing baseline reasoning	Prior exposure may elevate baseline scores or change how participants interpret and respond to intervention content, modifying the operation of mechanisms.	Measure at baseline and adjust for in analyses. In realist analysis, prior exposure will be examined as a contextual factor that may amplify, dampen, or alter mechanism activation.
Socioeconomic status (SES)	Confounder / Structural context: statistically treated as a confounder but understood as a contextual feature shaping capacity to engage	SES may correlate with campus allocation and influence baseline knowledge, perceived relevance of the program, and practical capacity to attend and engage with sessions.	Measure at baseline and include as a covariate. In realist interpretation, SES will be considered a structural context that may condition engagement and mechanism activation across clusters.
Baseline knowledge score	Covariate / Contextual anchor: statistically treated as a covariate and understood as a baseline contextual condition	Baseline knowledge reflects participants' initial knowledge, attitudes and behaviors and may shape how they interpret, engage with, and benefit from the intervention.	Include as a covariate in all models to adjust for initial differences. In realist analysis, baseline knowledge will be treated as a contextual anchor influencing the strength and direction of mechanism activation.

Figures

	Study period					
	<i>Enrolment 2026</i>	<i>Baseline 2026</i>	<i>Immediate post- 2026</i>	<i>3 months follow-up 2026</i>	<i>6 months follow up 2027</i>	
Timepoint	-T	T₀	T₁	T₂	T₃	2027
Cluster allocation	X					
Individual enrolment	X					
Eligibility screen	X					
Informed consent	X					
Intervention (CaRE program)		X				
Standard curriculum (both arms)		X				
Baseline survey		X				
Immediate post-intervention survey			X			
3 months follow-up survey				X		
6 months follow-up survey					X	
Waitlist control clusters						X

Figure 1

SPRIT diagram of CaRE program trial