Is trauma research risky? Investigating ethical challenges facing psychological trauma-related research

By

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Summary

Psychological trauma-related research raises ethical concerns, such as whether participation is highly distressing to participants (e.g., Jaffe et al., 2015; Newman et al., 2006). Although extant research has investigated some of these concerns (e.g., how participants react to answering trauma-related questionnaires; Jaffe et al., 2015), several important gaps remain. My thesis provides a new and original contribution to this literature by addressing three ethical concerns, framed here as research questions: (1) How *risky* is participating in experimental—or analogue—trauma-related research? (2) Do participants—including people with prior trauma-exposure—have unique ethical requirements, beyond what is outlined in current ethical guidelines, for participation in psychological research? (3) Are informed consent risk-warnings contributing to negative outcomes for participants in psychological trauma-related research?

Research Question One

Previous evidence from trauma questionnaire research indicates participation is generally well-tolerated by participants (e.g., Jaffe et al., 2015). But whether these findings extend to analogue trauma-related research (e.g., trauma film paradigm; James et al., 2016) and fit within IRB guidelines is unclear. Thus, I examined how participants reacted to viewing an analogue trauma film, including how this experience compared to other research participation (e.g., cognitive tasks) and everyday stressors (Chapter 3). Overall, relative to other participation conditions, participation in the trauma film condition was well-tolerated: participants reported low-to-moderate negative emotions, moderate benefits, and that participation was not worse than everyday stressors. Hence, analogue trauma-related research fits with minimal risk definitions (e.g., Public Welfare Act, 2018).

Research Question Two

I next investigated participants' views on consent guidelines and whether these views differed between trauma-exposed (i.e., according to the DSM-5 Criterion A for posttraumatic stress disorder) and non-trauma-exposed participants. Differing views would suggest that trauma-exposed people have unique requirements. I found (Chapter 5) participants were generally satisfied with current consent guidelines and made minor requests for change (e.g., greater consistency amongst consent forms). Notably, trauma-exposed and non-trauma-exposed participants expressed similar consent preferences, suggesting that current consent guidelines serve trauma-exposed participants. That is—in crowdsourced and undergraduate samples—unique considerations in ethical guidelines that describe trauma-exposed people as a vulnerable population are likely unwarranted.

Research Question Three

Finally, I examined whether the informed consent risk-warnings used in psychological trauma-related research contribute to adverse outcomes for participants (e.g., Abu-Rus et al., 2019). There was scant empirical evidence (Chapter 7) that addressed this concern, and that existing evidence was limited in several ways (e.g., no control condition). I subsequently developed recommendations for future research that I applied to three experiments investigating trauma-related consent risk-warnings and adverse outcomes. Overall, I found (Chapters 8 and 9) that consent risk-warnings did not cause participants to expect to experience warned of side-effects, nor to experience adverse outcomes (e.g., distress).

Together, my findings challenge ethical concerns about psychological trauma-related research. Methodologically, my thesis is an example for how to conduct psychological trauma-related research—particularly online—and provides advice regarding risk-management protocols. Theoretically, my thesis has implications for ethical and trauma-related research participation models. Practically and clinically, my research challenges IRB

and researcher apprehensions about trauma-related research (e.g., that trauma-related research is harmful), and provides recommendations for using consent risk-warnings in trauma-related research. My thesis also influences how ethical guidelines are developed and applied to psychological trauma-related research.

Declaration

I certify that this thesis:

1. does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university

2. and the research within will not be submitted for any other future degree or diploma without the permission of Flinders University; and

3. to the best of my knowledge and belief, does not contain any material previously published or written by another person except where due reference is made in the text.

Signed:

Date: 07.08.2024

Acknowledgment of Country

I wish to acknowledge that this body of work was produced on the lands of the Kaurna nation. I recognise the Traditional Custodians of the land where my research occurred and pay my respects to their Elders past, present, and emerging.

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Publications

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Stirling, N. S. J., Bridgland, V. M. E., & Takarangi, M. K. T. (2023). Nocebo effects on informed consent within medical and psychological settings: A scoping review, *Ethics & Behavior, 33*(5), 387-412.

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Takarangi, M. K. T., Moeck, E. K., Peters, J., & **Stirling, N. S. J.** (2022). Posttraumatic stress disorder symptom severity and functional impairment in the education domain. *Journal of Anxiety Disorders, 88.*[1]

[1] *Note.* This publication does not comprise part of my thesis work, but was a publication I worked on during my candidature.

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Chapter 1: An Overview of Psychological Trauma-Related Research and Research Ethics

Psychological research has some skeletons in its closet. Take for example the case of Little Albert, the infant who was classically conditioned to fear rats, yet—in a conditioning step too far—this fear generalised to other similar stimuli, such as rabbits (Meulders, 2020). Or, in the case of Zimbardo's prison experiment, where prisoners (i.e., participants) were teased and verbally abused, leading to early termination of the study (Haggerty, 2004). What these studies have in common—alongside other psychological research conducted in the 1900s (e.g., Milgrim's obedience trials)—is that they would now be considered unethical because they caused participants *significant* psychological harm (e.g., distress).

Thankfully, research ethics have substantially improved since then. Following the atrocities observed in World War II, namely Dr Mengele's egregious medical experiments, ethical guidelines—for the conduct of research with human subjects—were brought to the world stage (Gauthier & Pettifor, 2011). In 1947, The Nuremberg Code was established, outlining ten key ethical research principles, including informed consent (Leaning, 1996). In 1964, The World Medical Association used The Nuremberg Code as the basis for the Helsinki Declaration to establish the foundations of an independent review system; now recognised as Institutional Review Boards (IRBs; i.e., a committee or board of people that apply ethical guidelines when considering research proposals; Abu-Rus et al., 2019; Goodyear, 2007). Note that I will use IRB terminology throughout my thesis to generally represent ethics committees, ethical review boards, etc. Other notable research ethics documents have since been released, such as The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). Collectively, these ethical documents form the foundation for ethical guidelines we currently use in psychological research, such as guidelines in Australia (Australian Psychological

Society [APS], 2007; National Health and Medical Research Council [NHMRC], 2023), the United States (US; American Psychological Association [APA], 2017; Public Welfare Act, 2018), and the United Kingdom (UK; British Psychological Society [BPS], 2021). While further detailed discussion of these documents is beyond the scope of this thesis, I note that due to feasibility (i.e., ethical guidelines scope) and specificity (i.e., in interpreting results and considering application) challenges, I will only focus on guidelines governing Australia, the US, and the UK.

Australian, US, and UK ethical guidelines for psychological research jointly focus on four overarching principles (e.g., APA, 2016; NHMRC, 2023); albeit specific wording and detail varies. First, *beneficence* (or non-maleficence), meaning to avoid causing harm to participants, and instead, maintain participants' psychological welfare (APA, 2016; NHMRC, 2023). Second, *justice*; that is, to treat all participants fairly (e.g., ensuring participants have equal access to participate) and minimise discrimination (APA, 2016; NHMRC, 2023). Third, *respect*, for participant's rights—such as their right to freely provide informed consent—and to recognise each participant's intrinsic value, including to respect their sense of autonomy (APA, 2016; NHMRC, 2023). And fourth, *integrity*, meaning to conduct research honestly and in accordance with good practice (e.g., research being based on a thorough literature review, designing studies using methods appropriate to study aims; APA, 2016; NHMRC, 2023). Together, these principles are applied and upheld by researchers and IRBs to collectively safeguard participants' psychological welfare.

I will now consider these guidelines in the context of trauma-related research, defined here as research involving participants who have experienced autobiographical traumatic events, that asks participants about those events, and/or that involves exposing participants to

analogue trauma.[2] There are several reasons for why applying existing guidelines to trauma-related research is tricky. Though guidelines converge on the risk of harm to participants (e.g., BPS, 2021; NHMRC, 2023; Public Welfare Act, 2018), how harm and associated risks are defined is inconsistent and unclear. Indeed, a previous report aimed at improving IRB function identified that unclear definitions, such as harm, are one issue that complicates IRB review processes (Gunsalus et al., 2007). The US's *Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects* (Public Welfare Act, 2018) and the BPS's Ethical Guidelines (2021, p. 10) describe harm within a *minimal risk* context, meaning research is considered "minimal risk" if the risk and magnitude of harm is no greater than stressors encountered in everyday life or during performance of routine psychological examinations or tests. The BPS guidelines (2021, p. 10) helpfully provide specific examples of experiences that might exceed minimal risk definitions, such as research involving sensitive topics (e.g., people's sexual behaviour), and the induction of psychological stress, anxiety, or humiliation. Australia's *National Statement on Ethical Conduct in Human Research* (NHMRC, 2023) defines risk as the "potential for harm, discomfort, or inconvenience" (p. 12), and includes some examples of each category, though the guideline itself acknowledges these examples do not comprise an exhaustive list. Psychological harm examples include: "feelings of worthlessness, distress, guilt, anger or fear related, for example, to [*sic*] disclosure of sensitive or embarrassing information" (p. 13). Interestingly, an updated version of these guidelines released in 2023 saw the addition of "retraumatisation" to the psychological harm example list (NHMRC, 2023). Examples for discomfort include: "Minor side-effects of medication…and anxiety induced by an interview" (p. 13); and examples for inconvenience

[2] I acknowledge that there is ongoing discussion within the literature about how to define trauma and traumatic events (e.g., Galatzer-Levy & Bryant, 2013; Jones, 2021; Jones et al., 2022; McNally, 2003). For example, whether trauma—and symptoms associated with trauma exposure—strictly fit within DSM-5 criteria or expand to other experiences, such as bullying or loss of a loved one. This debate is however beyond the scope of my thesis. I therefore adopt the DSM-5 criterion-A (APA 2013) definition for traumatic event exposure within my own thesis work but acknowledge other research does not always adopt this definition.

include: “filling in a form…or giving up time to participate in research” (p. 13). Therefore, how ethical guidelines define harm varies, meaning there is no clear standard—even among countries that share similar ethical underpinnings—for how psychological harm is defined.

Another difficulty in applying the guidelines to trauma-related research is that trauma-related research is conveyed—within guidelines (e.g., BPS, 2021; NHMRC, 2023)—as being a sensitive area of investigation. Other sensitive areas of investigation are, for instance, about sexual, legal, and/or political behaviour (e.g., BPS, 2021; Yeater et al., 2012). Indeed, some ethical guidelines “normally…consider” sensitive research topics as being greater than minimal risk (BPS, 2021, p. 10). Consequently, by default, the ethical principle *beneficence* (i.e., avoiding causing harm) is likely challenged by ethical guidelines. Even through the National Health and Medical Research Council’s (2023) addition of “retraumatisation” to psychological harm examples, we see that guidelines suggest trauma-related research is inherently harmful to participants. Therefore, based on current guidelines, psychological trauma-related research may be intuitively identified as *risky* to participants because it concerns a sensitive topic, even if available evidence suggests otherwise (e.g., Jaffe et al., 2015).

We then enter IRBs into the mix. IRB members have the difficult task of interpreting and applying guidelines to determine likelihood of *risk*—that is, the level of harm a psychological trauma study may pose to participants—and weighing risk against potential benefits (e.g., Haggerty, 2004; Newman et al., 2001; NHMRC, 2023). It is difficult for IRBs to base their decision-making processes about potential harms on an empirical basis or “actuarial framework” (Haggerty, 2004) because there is a small—and somewhat limited available literature (i.e., most research has focused on trauma questionnaire research; Jaffe et al., 2015)—on the potential, magnitude, and types of harms arising from psychological trauma-related research. Instead, some researchers and IRBs likely rely on their own

knowledge and experiences, using a measured-guessing (e.g., by imagining themselves in the participant's place) or intuitive approach to assess potential psychological harms (Carter-Visscher et al., 2007; Haggerty, 2004; Smith & Anderson, 2022). Together, these decision-making strategies may result in base-rate errors, estimates of harm being based on salient outcomes versus risk probability (Newman et al., 2006), risks being determined on a "pre-cautionary" basis instead of actuarial risk (Haggerty, 2004), or the introduction of assumptions to psychological research (e.g., that participants will be greatly harmed if asked about prior traumatic experiences; e.g., Jaffe et al., 2015).

Finally, judgments about psychological harms may be challenging for IRBs because, unlike medical-based outcomes, and outside a research setting, trauma is subjective and difficult to define (e.g., Galatzer-Levy & Bryant, 2013; Jones et al., 2023; Jones & McNally, 2022; McNally, 2003). Though, for the purposes of my empirical studies, I use DSM-5 Criterion A to measure trauma exposure in an objective way. For instance, one person may judge viewing a sexual assault scene—like those used in the trauma-film paradigm (James et al., 2016)—as uncomfortable, while another person may judge this same experience as traumatic and/or harmful. Indeed, we know from prior research that people use the consequences of other peoples' events—i.e., prior experiences—to judge what those experiences were like for the person (e.g., that a traumatic experience caused someone personal growth or brought about harm; Burnell & Garry, 2021). Other research shows that people exposed to a broad trauma definition (e.g., "scientists define trauma as any event which could cause intense distress to a person") were more likely to evaluate a trauma film clip as being traumatic than people exposed to a narrow definition (e.g., "scientists define trauma as very rare, horrifying events, such as witnessing the murder of innocents"; Jones & McNally, 2022). Thus, the subjectivity of trauma likely complicates IRB members' risk assessments of psychological harm attached to trauma-related research.

Altogether, it is perhaps unsurprising that some IRB members are apprehensive (e.g., Legerski & Bunnell, 2010; Yeater et al., 2012) about psychological trauma-related research because they assume it is highly risky (e.g., that being asked about prior trauma history could cause suicidality; Jaffe et al., 2015). Certainly, previous research documents several concerns, including that psychological trauma-related research may retraumatise participants (Jaffe et al., 2015; Legerski & Bunnell, 2010; Newman et al., 2006; Weiss, 2021), cause severe (Yeater et al., 2012)—and long lasting—distress (Becker-Blease & Freyd, 2006; Jaffe et al., 2015; Legerski & Bunnell, 2010), and be riskier with unique harms—compared to other types of psychological research (Carter-Visscher et al., 2007; Newman et al., 2006; Yeater et al., 2012). Other concerns focus on trauma-related research potentially worsening existing post-traumatic stress (PTS) symptoms (Abu-Rus et al., 2019; Jaffe et al., 2015), that prior trauma exposure means people may be more vulnerable as research participants (Carter-Visscher et al., 2007; Newman et al., 2006), and that they may be harmed because of participation (DePrince & Freyd, 2006; Ferrier-Auerbach et al., 2009; Jaffe et al., 2015; Yeater & Miller, 2014; Yeater et al., 2012). Interestingly, several of these concerns parallel community-held stereotypes about trauma, such as worries over how emotionally predictable and/or stable trauma-exposed people are, or that "people exposed to serious trauma are damaged" (Clapp et al., 2023, p. 12). Hence, such concerns about trauma-related research may also reflect IRB members' personal beliefs and biases (see Pritchard, 2011 for other decision-making biases that may contribute to IRB decision variability).

The tendency for some IRBs to focus on risks of harm—even remote possibilities (Haggerty, 2004)—may mean research benefits are overlooked. Indeed, IRB members more generally:

> Admit they operate under constant concern about the one case in a thousand that might slip through review—with the consequence that the other 999 receive exaggerated reviews and risk rejection in an effort to err on the side of caution. (Gunsalus et al., 2007, p. 2)

Yet, when reviewing trauma-related research proposals, IRBs should consider potential research benefits and how these benefits weigh against risks of harm (e.g., NHMRC, 2023). Although benefits—and risks—differ between research proposals, possible benefits range from empowering people and providing them with positive learning opportunities (e.g., by normalising trauma reactions, offering people a supportive place to disclose sensitive information), to improving scientific knowledge and intervention (e.g., of posttraumatic stress-like [PTS] reactions; Newman & Kaloupek, 2004). For example, prior research shows participants benefit from disclosing and writing about their prior trauma, if done in a supportive environment (e.g., Pennebaker, 1997; Rubin et al., 2010).

There is however evidence to suggest that IRB apprehensions—and their focus on risk—practically impacts trauma-related research conduct. Prior research found that IRBs were more likely to reject ethical scenarios when the scenarios examined sensitive topics (versus non-sensitive topics; Ceci et al., 1985). Another study, on 114 US-based trauma researchers' experiences with IRBs, found most (61.4%) researchers reported that their IRB had raised concerns with them over asking participants questions about prior traumatic experiences, with a further 13.3% explaining their IRB had rejected their ethics application due to similar concerns (Jaffe et al., 2015). Hence, in some cases, trauma-related research may not proceed, because of IRB concerns, subsequently limiting advancements in trauma-related knowledge and treatment for trauma-exposed populations (Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Jaffe et al., 2015). Selectively limiting trauma-related research may also contribute to the idea that traumatic experiences—such as child abuse—should not be discussed because they are perceived as "taboo" (Becker-Blease & Freyd, 2006, p. 223;

Bussell, 2017; Newman et al., 2006). Further, IRB apprehensions may mean trauma-exposed people are denied the opportunity or *choice* to contribute their experiences to our understanding of trauma (Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Newman et al., 2006). In other instances, trauma researchers have reported difficulties gaining approval to use commonly employed, gold-standard trauma measures (Yeater & Miller, 2014), being advised by their IRBs to change trauma measures (e.g., make abuse history measures less detailed; Jaffe et al., 2015). Methodologically-speaking, altering study design due to fear of asking people about their trauma may lead to invalid data (i.e., not adequately answering the research question), meaning participants' time has not been respected and resources potentially wasted.

Though there is certainly no easy solution to address ethical challenges arising in the context of trauma-related research (see Gunsalus et al., 2007 for a comprehensive report on several other issues affecting our ethical review system, including IRBs), one way to better support researchers, IRBs, and policymakers is to empirically address ethical concerns (e.g., Newman, 2008). For instance, providing researchers and IRBs with evidence about how people respond to participation in psychological trauma-related research (e.g., how they respond to research participation that involves viewing an analogue trauma) will provide evidence for the *actual risk* trauma studies carry. Indeed, some research has examined the implications of asking participants about their prior traumatic experiences, such as whether this participation experience retraumatises participants (e.g., Jaffe et al., 2015; see Weiss, 2021 for review and Chapter 2).

But several important gaps remain. First, it is unclear how participants react to trauma-related research that uses analogue trauma paradigms (e.g., trauma film; James et al., 2016), rather than asks about their prior traumatic experiences. Second, it is unclear whether the informed consent process aligns with *participant* preferences, and specifically, whether

trauma-exposed participants (i.e., per Criterion A definition for a diagnosis of posttraumatic stress disorder [PTSD]; APA, 2013) have different requirements regarding consent. If trauma-exposed participants had different preferences to non-trauma-exposed participants, such difference may suggest that trauma-exposed participants should be recognised as an ethically vulnerable population that requires special precautions, as suggested for universally vulnerable populations (e.g., children, prisoners). Finally, little is known about how informed consent risk-warnings (i.e., risk information communicated via informed consent that warns of potential side-effects associated with participation) affect participants in trauma-related research. For instance, some researchers have raised the concerning possibility that side-effects communicated via risk-warnings may cause participants negative outcomes, compared to if they had not encountered such a risk-warnings (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Loftus & Fries, 1979; Loftus & Teitcher, 2019). As Newman, Risch, and Kassam-Adams (2006) note, "all ethical dimensions of trauma-related research need empirical attention so that research on trauma can continue to be a win-win situation for all stakeholders" (p. 42-43). Hence, it is critical that researchers continue building a trauma-related research evidence base to help inform trauma-related research practices and IRB decision-making processes.

Overall then, my thesis aims to contribute to the existing—yet small—empirical literature regarding ethical concerns in psychological trauma-related research. Due to scope, my thesis will focus on three lines of ethical concern—framed here as research questions—arising in the psychological trauma-related research context. I will address these research questions, in turn, over several chapters. In Chapters 2 and 3, I will address Research Question One: How risky is participation in experimental—or analogue—trauma-related research? In Chapters 4 and 5, I will cover Research Question Two: Do participants—including people with prior trauma exposure—have unique ethical requirements, beyond

current ethical guidelines, for participation in psychological trauma-related research? Finally, across Chapters 6 to 9, I will explore Research Question Three: Are informed consent risk-warnings contributing to negative outcomes for participants in psychological trauma-related research? I note that because most of my central thesis chapters are articles designed to stand alone, there is some unavoidable repetition of concepts and ideas throughout my thesis.

Chapter 2: Research Question One: How Risky is Participation in Experimental—Or Analogue—Trauma-Related Research?

Recall that several researcher and IRB concerns centre on the idea that psychological trauma-related research may cause significant harm to participants, such as distress (e.g., Jaffe et al., 2015; Newman et al., 2006; Yeater et al., 2012). Other concerns relate to the idea that psychological trauma-related research may be *riskier* than other psychological research types (e.g., Yeater et al., 2012), or that some trauma research participants may be uniquely vulnerable given prior trauma exposure and/or PTS-like symptomology (e.g., Jaffe et al., 2015; Yeater et al., 2012). To date, most research seeking to address these concerns has examined how people react to being asked about their prior traumatic experiences, including childhood maltreatment, via self-report questionnaires and to a lesser extent, via interview (i.e., providing people the opportunity to discuss their trauma). I will first review this literature within the context of researcher and IRB concerns.

Do Most Participants Experience Significant Distress in Trauma-Related Research?

Over the past decade or so, trauma researchers have sought to understand whether—in a research setting—asking participants about their prior traumatic experiences and/or trauma causes them to experience distress (e.g., Jaffe et al., 2015; Newman et al., 2006). Distress has been operationalised in various ways (e.g., Positive and Negative Affect Scale [PANAS], Reactions to Research Participation Questionnaire [RRPQ], single-response emotion items [e.g., about feeling upset], simply asking participants how distressed they are; e.g., Carter-Visscher et al., 2007; DePrince & Chu, 2008; Fortier et al., 2020; Griffin et al., 2003; Yeater et al., 2012), study design has varied from experiments (e.g., Yeater et al., 2012) to descriptive studies (e.g., administering several questionnaires to participants; e.g., Edwards et al., 2009), and samples have differed (e.g., undergraduate, community, clinical). Yet researchers converge on a similar conclusion: most participants typically report low-to-

moderate distress levels, suggesting they tolerate participation well (Carter-Visscher et al., 2007; DePrince & Chu, 2008; DePrince & Freyd, 2006; Edwards et al., 2009; 2014; Fortier et al., 2020; Hebenstreit & DePrince, 2012; Kilpatrick et al., 2007; Newman et al., 1999; Resick et al., 2009; Yeater et al., 2012). This conclusion fits with findings from Jaffe and colleagues' (2015) multi-purpose meta-analysis that examined people's reactions to participation in trauma-related research. Of 73,959 (73.4% female; 26.6% male) participants—comprising undergraduate, community, and clinical samples asked about their traumatic experiences (e.g., sexual or physical assault)—participants generally reported low-to-moderate distress (i.e., ~ 2.3 on a 5-point scale, where *1 = Minimal distress and 5 = Extreme distress*; Jaffe et al., 2015).

Several studies find a diverging pattern of results (e.g., Johnson & Benight, 2003). For instance, just over a third (30.96%; $N = 323$) of a South African undergraduate student sample reported marked distress after answering questionnaires related to prior child abuse experiences (Bassa & Collings, 2012). The authors highlighted that participants' average distress rating (rated on the RRPQ Emotional Reactions subscale) was at the higher end of distress estimates found in other trauma-related research (e.g., Newman et al., 2006), and was comparable to prior distress ratings—i.e., how upset people were by responding to trauma-based interview questions—reported by *psychiatric inpatients* (Carlson et al., 2003). One reason for Bassa and Collings' alternative findings may be cultural and/or experiential differences between students from South Africa and the United States (e.g., Yeater et al., 2012).

In another divergent example (Griffin et al., 2003), just under half (~ 44%) of participants reported moderate-to-strong distress when they recounted their prior traumatic experience while physiological measurements, such as heart rate, were taken. But participants' distress decreased *after* this phase of the study, suggesting the elevation in

distress was transitory and linked to methodology (i.e., recalling experience with physiological measures). In a final example study where distress ratings differed from overall low-to-moderate distress reports, such distress seemed to depend on assessment task (Resick et al., 2009). Participants reported more distress when discussing their prior traumatic experience with researchers, than when completing an overall psychophysiological assessment (e.g., comprising blood and saliva collection, startle response assessment), or completing trauma/psychopathology-related questionnaires (Resick et al., 2009). The authors suggested that participants were more distressed when discussing their traumatic experience(s) because they were asked to discuss memories they may have been avoiding, in line with their PTSD diagnosis. Hence, the assessment task used in trauma-related research may alter participant distress reports. Together, the literature suggests that most participants report low-to-moderate distress when participating in trauma-related research, with some participants reporting greater distress—likely due to different samples and assessment types.

Do Participants Report Benefits to Trauma-Related Research Participation?

Mirroring an IRB research proposal evaluation process, researchers have also considered the other side of the ethical coin—benefits—when addressing distress-related concerns. Much like distress, researchers have operationalised benefits in multiple ways, from asking participants single-item questions (e.g., about how interesting, beneficial, enjoyable the research was or whether they would be willing to participate again; e.g., Carter-Visscher et al., 2007; Griffin et al., 2003), to administering the RRPQ personal benefits and Posttest Reactions Questionnaire positive reaction subscales (e.g., extent of agreement with statements such as “I gained something positive from participating”; DePrince & Chu, 2008; Edwards et al., 2009; 2014; Yeater et al., 2012). More generally, benefits can be attached to the specific study (e.g., “I gained something positive from participating”, Posttest Reactions Questionnaire; e.g., Yeater et al., 2012) and/or to trauma-related research more generally

(e.g., whether it is a good idea to include trauma-related questions in research; e.g., DePrince & Freyd, 2006). Overall, Jaffe and colleagues' (2015) meta-analysis reveals that participants, on average, report moderate-to-high benefits (i.e., 2.4 on a 5-point scale, where *1 = Most beneficial and 5 = Least beneficial*). Some studies find participants still report benefits or gains to participation, but only in approximately half (Bassa & Collings, 2012), or less than half of their samples (Johnson & Benight, 2003; Sandberg et al., 2012; Newman et al., 1999). Moreover, even when participants report distress, they report they still would have participated or would be willing to participate again (e.g., Carter-Visscher et al., 2007; Ferrier-Auerbach et al., 2009; Griffin et al., 2003; Resick et al., 2009; Walker et al., 1997), and have minimal regret regarding participation (DePrince & Freyd, 2006; Jaffe et al., 2015; Newman et al., 1999).

Researchers have also considered risks and benefits concurrently via cost-benefit ratios. Doing so not only provides a more holistic view of harm judgments (e.g., by considering potential negative psychological side-effects, such as distress, *alongside* perceived benefits), but also provides IRBs and researchers with actuarial data that informs risk-benefit considerations. In one example, researchers examining undergraduate and community samples found a favourable cost-benefit ratio: participants rated benefits—conceptualised as topic importance (i.e., trauma) and whether it was a good idea to include these questions in psychological research—significantly higher than costs (i.e., distress; DePrince & Freyd, 2006). Similarly, undergraduate and community participants reported that the personal benefits associated with answering trauma-based questionnaires significantly outweighed the costs (i.e., emotional reactions and drawbacks), irrespective of whether participants answered questions via questionnaire or interview (DePrince & Chu, 2008). Similarly, in a trauma-exposed (i.e., self-reported childhood sexual assault and/or adult sexual assault) and non-trauma-exposed college sample, the participation benefits—measured

via the RRPQ personal benefits subscale (e.g., “I gained insight about my experiences through research participation")—statistically outweighed the costs—measured via the RRPQ Emotional Reactions subscale (e.g., “I was emotional during the during the research session”; trauma-exposed: *Cohen’s d* = 0.53, non-trauma-exposed: *d* = 0.89; Edwards et al., 2009). These findings hold for people who have experienced domestic violence (Hebenstreit & DePrince, 2012) and child abuse (Bassa & Collings, 2012). Further, informal (i.e., nonstatistical) weighing of cost against benefits findings, within empirical articles and associated systematic or narrative literature reviews, show a similar favourable ratio cost-benefit ratio (Cromer et al., 2007; Ferrier-Auerbach et al., 2009; Jaffe et al., 2015; Newman & Kaloupek, 2004; Yeater et al., 2012).

Taken together then, extant literature supports the idea that participants generally tolerate participation in trauma-related research well, albeit a few people report greater than neutral distress ratings. Even when they report distress, most participants report benefits to participating (e.g., personal benefits), would be willing to participate again, and have minimal-to-no regret regarding participation. But do these findings hold across trauma research-relevant considerations? For example, do they hold for people reporting the highest (i.e., above the midpoint on a Likert-type measure) distress ratings within a sample, for people who have previously experienced a traumatic event, or for people who are either currently diagnosed with or experiencing PTSD-like symptoms? IRBs may be particularly concerned about these participants in relation to trauma-related research (e.g., that asking about prior trauma might significantly psychologically affect people with PTSD or PTSD symptoms; Jaffe et al., 2015).

What About Reactions in Participants who Report the 'Highest' Distress Ratings in a Relative Sample?

One way to examine distress in trauma-related research is to consider participants who report the *highest* distress ratings within a sample, such as above the midpoint on a distress-related measure (e.g., if 5 represents moderate distress on a Likert-type scale and 10 equals extreme distress, then participants who respond between 5 and 10 are specifically examined). Yeater and colleagues (2012) randomly allocated undergraduate participants (N = 504) to either respond to >300 trauma/sex-related questions (e.g., regarding rape, trauma symptoms, childhood maltreatment), or complete basic cognitive tasks (e.g., Raven's Matrices). Five (2.1%) cognitive task participants, and nine (3.4%) trauma/sex questionnaire participants reported negative reactions above the midpoint (i.e., above 4, on a scale where *1 = Strongly disagree and 7 = Strongly agree* with negative emotion statements). Yet, closer inspection of the means showed most of these participants were slightly to moderately distressed, with approximately three participants in the moderately distressed range (i.e., maximum score was 5.52). Hence, Yeater and colleagues' findings indicated that even for participants reporting the highest distress ratings, such ratings were not at ceiling.

Further, prior research has considered participants who report the highest distress ratings alongside reported benefits to participation (e.g., believing the research is important). In a study examining college women's reactions to answering sexual assault questionnaires, only 4% (n = 43) of participants "agreed" or "strongly agreed" with negative Emotional Reactions items on the RRPQ subscale (Edwards et al., 2009). However, many of these participants still reported that personal benefits outweighed costs to participating, that they would have still participated even knowing what they know now, and that they believed the research was for a good cause (Edwards et al., 2009). Further, across undergraduate and community samples, 5.4% (n = 8) of community participants and 6.4% (n = 30) of

undergraduates judged that answering trauma-related questionnaires was “much more distressing” than other things they sometimes encountered in day-to-day life (DePrince & Freyd, 2006). A further 27.5% (*n* = 41) of community participants and 25% (*n* = 117) of undergraduates reported participation was “somewhat more distressing”. But of these 196 participants, only one participant reported a low importance rating when asked to evaluate how important they believed it was for psychologists to ask about trauma-related events in research. In fact, most participants agreed that it was important for psychologists to ask about trauma-related events and that it was a good idea to include such questionnaires in psychological research. Together, it seems participants either numerically do not report distress ratings at ceiling or, if they do report higher ratings, the research merits—or benefits—outweigh such distress.

What About Reactions in Trauma-Exposed Participants?

Another trauma research-relevant consideration is how trauma-exposed participants react to participation in trauma-related research. Note, trauma-exposure definitions vary within the literature and thus I attach definitions to the corresponding studies below. Similarly, recall reported benefits can be operationalised as being attached to the study and/or as being attached to trauma-related research more generally.

In one example study, non-trauma-exposed college-aged women (i.e., those who did not self-report experiencing childhood or adult sexual assault) reported significantly less severe negative emotional reactions (measured via the RRPQ) than trauma-exposed participants, when answering trauma-related questionnaires (e.g., about sexual assault, trauma symptoms; Edwards et al., 2009). Trauma-exposed participants—participants reporting only adult sexual assault or both childhood and adult sexual assault—also reported significantly more personal benefits to participating than non-trauma-exposed participants did. Moreover,

trauma-exposed participants' mood (e.g., anger, confusion) remained heightened throughout research participation, compared to non-trauma-exposed participants.

In another example, DiLillo and colleagues (2006) examined undergraduate women's reactions to answering questionnaires about childhood abuse and whether reactions differed based on assessment type (i.e., computer, pencil-and-paper versus interview). Overall, trauma-exposed participants (i.e., who self-reported prior sexual or physical childhood abuse) reported experiencing more mood/emotion change compared to when they first started the study, and feeling more uneasy or upset—particularly those in the computer-administered assessment condition—than non-trauma-exposed participants (i.e., greater distress; DiLillo et al., 2006). However, participants also expressed a preference for computer-administered assessment and indicated it was the most confidential way to assess childhood abuse. Therefore, trauma-exposed undergraduates may report greater distress than non-trauma-exposed participants—depending on assessment type—and still report other ethical benefits (e.g., confidentiality associated with assessment) alongside such distress.

Furthermore, DePrince and Freyd (2006) compared reactions to trauma-related research between people who self-reported experiencing interpersonal violence and people who did not, and then between people who reported sexual physical abuse occurring before the age of 18 and people who did not. Participants reporting previous interpersonal violence—across both community and undergraduate samples—judged it was more important that psychologists investigate trauma, than participants who had not experienced interpersonal violence. Similarly, undergraduates reporting prior abuse believed it was more important that psychologists ask about trauma than did non-abuse participants. Therefore, these studies indicate that distress may be somewhat elevated in trauma-exposed, compared to non-trauma-exposed participants, but that trauma-exposed participants also report more participation benefits.

There are however some challenges to interpreting these findings. For instance, how trauma-exposure is defined differs between studies, as does how trauma research-related participation is measured (e.g., distress, reported benefits). To overcome some of these limitations, I turn to Jaffe and colleagues' (2015) meta-analysis, which specifically aimed to investigate whether participants' reactions to trauma-related research differed due to personal characteristics, such as people reporting a personal victimisation history. The studies included traumatic events such as child maltreatment, sexual or physical assault, intimate partner violence, crime, terrorist attacks, military combat, motor vehicle accidents, and natural disasters. In a sample comprising n = 50,615, trauma-exposed participants, on average, reported significantly more distress than non-trauma-exposed participants; a small effect (*Hedge's* g = 0.31). But in both trauma-exposed and non-trauma-exposed participants, overall mean distress was < 3 (i.e., on a 5-point scale where *1 = Minimal distress and 5 = Extreme distress*), suggesting that trauma-exposed participants did not report severe distress (i.e., at ceiling). Trauma-exposed and non-trauma-exposed participants did not differ on benefits (g = 0.04; ~ 2 on a scale where *1 = Most beneficial and 5 = Least beneficial*) or global evaluations (e.g., "I believe this study's results will be useful to others"; g = 0.04); recall, on average, overall reported benefits were moderate-to-high. Notably, while not statistically significant, trauma-exposed participants reported higher distress than non-trauma-exposed participants when their personal trauma was sexually related rather than non-sexually related (sexual trauma: g = 0.04, non-sexual trauma: g = 0.45). Further, trauma-exposed participants reported significantly greater distress when answering trauma-related questionnaires via interview (g = 0.74), versus other methods (g = 0.24; e.g., completing questionnaires by pen-and-paper).

A related, but different, trauma-exposure operationalisation is how many traumatic events people have been exposed to. One study's findings suggest that exposure frequency may influence reported distress. Specifically, Resick and colleagues (2009) found that

participants with a sexual/physical revictimization history (i.e., repeated traumatic incidents) reported higher distress when responding to trauma-related interviews and questionnaires, than participants who reported previously experiencing one isolated traumatic event (Resick et al., 2009). But another study's findings signal that exposure frequency may *not* influence reported distress in trauma-related research. DePrince and Chu (2008) found that trauma exposure was unrelated to cost-benefit ratio and positive research evaluation differences. Thus, trauma-exposure frequency is one factor that may influence how people react to trauma-related research, but the limited extant research has produced somewhat mixed findings.

What About Reactions in Participants who Report PTSD-Like Symptomology?

Another relevant consideration is participants diagnosed with PTSD and/or who report any PTSD symptoms. One of Jaffe and colleagues' (2015) aims was to investigate how people with PTSD symptoms[3] (i.e., inclusion criteria were participants diagnosed with PTSD and/or who reported PTSD symptoms) reacted to trauma-related research participation. Overall, participants with PTSD symptoms typically reported greater distress than participants without PTSD symptoms ($g = 0.57$). Participants with PTSD symptoms reported distress > 3 (i.e., on a 5-point scale where *1 = Minimal distress and 5 = Extreme distress*), suggesting moderate-to-high distress. There was also a greater association between distress and PTSD symptoms for participants who answered questionnaires via interview ($g = 0.96$), than other methods ($g = 0.52$). Regarding reported benefits, people with and without PTSD symptoms reported *similar* trauma-related research benefits ($g = 0.10$). PTSD symptoms were also unrelated to participant regret or coercion. Further, despite concern that sexually-related trauma participation may be more distressing to people with PTSD symptoms (e.g., Griffin et

[3] Jaffe et al.'s meta-analysis included studies examining PTSD diagnosis (e.g., Figley et al., 2004; Parslow et al., 2000) and studies that measured symptom severity (e.g., Edwards et al., 2014; Gariti et al., 2009). The results refer broadly to PTSD severity, therefore, for ease, I refer to people reporting PTSD symptoms (or not).

al., 2003; Nielsen et al., 2016), the link between distress and PTSD symptoms was greater for studies that focused on *non-sexually-related* trauma ($g = 0.96$), than sexually-related trauma ($g = 0.52$).

The idea that people experiencing PTSD-like symptomology report greater distress, relative to people without PTSD-like symptomology, is perhaps unsurprising. Previous research indicates that more severe PTSD symptoms—such as intrusive thoughts, avoidance, and negative emotions—are related to more distress (Marshall et al., 2010; 2019). Moreover, elevated distress reflects the distress-related criteria (i.e., Criterion B, C, and G) listed in the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5; APA, 2013) for a PTSD diagnosis. Thus, the heightened distress people experiencing PTSD-like symptomology report may simply reflect their symptoms, rather than the trauma-related participation experience itself.

There are also drawbacks of the extant literature, making it difficult to ascertain how trauma-related research participation affects participants. For example, Jaffe et al. (2015) noted that 87% of included studies measured distress *after* participation (i.e., after answering questionnaires), meaning there is no baseline (e.g., distress, anxiety) for comparison. As such, we do not know if, and to what extent, participants were already distressed when commencing participation. Moreover, although Jaffe et al. were inclusive in how they operationalised trauma-exposure and PTSD definitions, to account for variability in definitions across different studies, we do not know whether trauma-exposure type, diagnosis, or symptom severity is more important. Relatedly, while methodologically and ethically challenging to conduct, few studies within this literature are experimental. It is therefore difficult to draw causal conclusions about what factor/s might be contributing to distress and/or harm observed in studies. For instance, perhaps individual differences such as age or personality traits—as some prior limited research has investigated with mixed findings (e.g.,

DePrince & Chu, 2008; Rinehart et al., 2017)—contribute to participant distress. Alternatively, as Jaffe et al. suggest, maybe completing multiple measures asking about sensitive topics has a "cumulative emotional impact" on participants (p. 53). Together, it is unclear whether the *trauma-related* participation experience alone contributes to reported distress or if another factor, outside the research itself, contributes to distress ratings.

Comparisons Between Trauma-Related Research Participation and Everyday Stressors

Recall that according to US guidelines, one standard to determine the potential risk of harm to participants—or whether research exceeds the *minimal risk* definition—is to compare participation to everyday stressors. To collect evidence that directly speaks to this risk benchmark, some researchers have asked participants to compare their trauma-related participation experience (i.e., that involves responding to trauma-related questionnaires and/or discussing prior traumatic experiences) to everyday stressors. Note that studies operationalise comparisons to everyday stressors differently.

Some participants have compared participation to "other things" they may encounter in day-to-day life. In DePrince and Freyd (2006), participants asked to compare answering trauma-related questionnaires to "other things" indicated their participation was no worse (i.e., neutral) than these other things. Here, women reported statistically significantly higher scores than men, meaning that women felt participation was somewhat worse than other things they encountered (d = 0.15; DePrince & Freyd, 2006).[4] In another example, Cromer and colleagues (2006) asked undergraduate participants to compare how distressing it was to complete questionnaires regarding SAT/GPA, body image, and emotional and sexual abuse, compared to other things they sometimes encountered in everyday life. Here, participants reported answering these questionnaires collectively as being somewhere between "somewhat more distressing" and "neutral" than other things in everyday life (Cromer et al.,

[4] I note overall that Jaffe and colleagues (2015) did not find differences in *distress* reactions by gender.

2007, Study 1). However, these questionnaires (e.g., SAT/GPA, body image) *did not* statistically differ from one another on distress ratings, indicating that it was not specifically the *trauma*-related questionnaires (i.e., about emotional and sexual abuse) that prompted the "somewhat distressing" endorsement. Instead, these findings suggest that questions about SAT/GPA and body image—while not necessarily considered distressing by IRBs—may be perceived by undergraduates as slightly more distressing than other things in everyday life. However, asking participants to compare participation to "other things" is limited because the comparison is vague (i.e., we do not necessarily know what people are anchoring their comparisons against).

Yeater and colleagues (2012) overcame this limitation by asking undergraduate participants to compare participation in trauma-related research to specific everyday stressors, such as having a cavity drilled by the dentist. When undergraduate participants compared answering trauma/sex-related questionnaires to such specific everyday stressors, they reported the stressors were *worse* than participation ($d = 0.14$; Yeater et al., 2012). Thus, these preliminary studies indicate that asking participants to respond to trauma-related questionnaires does not exceed minimal risk definitions.

Comparisons Between Trauma-Related Research and Other Psychological Research Types

Because of existing stereotypes about trauma (e.g., trauma-exposed people as being "damaged"; Clapp et al., 2023), in isolation, it is understandable why psychological trauma-related research appears riskier than other psychological research types. However, comparing participants' reactions to answering trauma-related questionnaires against other questionnaire and psychology study types (e.g., basic cognitive tasks assessing memory or attention that IRBs may consider as being minimal risk research) suggests trauma research may be no riskier than other research types. When Yeater and colleagues (2012) compared participant

reactions between responding to sex/trauma-related questionnaires and completing cognitive tasks (e.g., Raven's Matrices), they found that participants who completed sex/trauma-related questionnaires reported lower mental costs (d = 1.09) and more benefits (d = 0.39), but more negative emotions (d = 0.39). However, the means for negative emotion were low in both conditions—suggesting no-to-minimal distress—and positive emotions were similar between conditions (i.e., not statistically significant). In fact, participants who responded to sex/trauma-related questionnaires reported higher positive affect post-participation than participants who completed cognitive tasks. In another example, recall Cromer and colleagues (2006) had participants answer questionnaires about different topics (e.g., SAT/GPA, physical and emotional abuse). In Study 1, participants rated these different topics—including physical and emotional abuse—as similar on distress; in Study 2, participants rated the sexual abuse questions as "more distressing" than parental income and sexual orientation questions. However, answering questionnaires about what race meant to them was *similarly* distressing as answering questionnaires about sexual abuse. For the race and sexual abuse topics, participants—on average—rated answering questionnaires somewhere between "somewhat more distressing" and "neutral" compared to everyday stressors. In a final example, Fortier and colleagues (2020) found that participants more frequently reported questions about parenting (5.3%, n = 53), than questions about childhood maltreatment (4%, n = 40) as being upsetting. Therefore, direct comparisons made between trauma-related research and other research, or between sensitive topic types, suggest that psychological trauma-related research is not uniquely risky—or distressing.

Indirectly, previous research also indicates that research topics other than trauma can be distressing to participants (Jorm et al., 2007). A systematic review about participant distress in psychologically sensitive research (e.g., participants asked about previous traumatic experiences, experiences with psychosis or depression) highlighted that people

reported questions about finance were distressing. Moreover, children and adolescents found answering questionnaires regarding substance use, and older adults evaluated cognitive impairment tests, as distressing (Jorm et al., 2007).

Taken together, despite some drawbacks of research examining how participants react to trauma-related research participation (e.g., few studies employing experimental designs), the evidence indicates participation is generally well-tolerated. Participants usually report benefits, believe that the research is important, and tend not to report regret; albeit a minority of participants deviate in these reports. While participants reporting trauma exposure and/or PTSD-like symptomology indicate somewhat greater distress (versus non-trauma-exposed participants and/or participants not reporting PTSD-like symptomology), overall distress is still moderate. But recall that this extant literature has focused on how people react to being asked about their prior traumatic experiences, such as childhood maltreatment, predominantly via self-report questionnaires and interview. Therefore, whether these previous findings extend to other psychological trauma-related research types is unknown.

What About Other Psychological Trauma-Related Research Types?

Another form of psychological trauma-related research involves simulating traumatic experiences for participants (i.e., analogue trauma). For instance, the trauma film paradigm involves exposing participants to trauma material (e.g., a film depicting a rape scene) to cause temporary, PTSD-like symptoms—such as intrusive memories—to allow trauma researchers to examine PTSD-like symptomology within a controlled setting (e.g., exposure to same trauma type; Holmes & Bourne, 2008; James et al., 2016). Despite the widespread use of analogue trauma paradigms, little is known about how participants react to—in an ethical sense (e.g., risk of harm via distress, benefits)—participation in such studies. In one study akin to an analogue trauma design, Carter-Visscher and colleagues (2007) found trauma-exposed participants (i.e., had experienced childhood maltreatment) reported greater distress

in session one—when answering questions regarding childhood maltreatment—than in session two—when being exposed to negatively arousing sounds/images—or session three—when answering questions regarding their reactions to participation. This finding might suggest that exposing participants to an analogue trauma would be less distressing than answering trauma-related questionnaires. But to date, no empirical research has examined this possibility, let alone how participants react to participating in an analogue trauma study. I will therefore aim to address this gap in Chapter 3 of my thesis by examining how participants react to and evaluate participation in an analogue trauma film study.

Chapter 3: No more than discomfort: The trauma film paradigm meets definitions of minimal risk research[5]

Author contributions: I cleaned the data for analysis, and performed the data analysis and interpretation. I drafted the manuscript, and MKTT and RDVN provided critical revisions. MKTT developed the study design and DN, JO, DG, and RS collected the data as part of a larger project. MKTT and RDVN approved the final version of the manuscript for submission.

Abstract

Despite IRB concerns about psychological harm arising from research participation, evidence from trauma-questionnaire research suggests that participation is typically well-tolerated by participants. Yet, it is unclear how participant experiences of in-lab trauma simulations align with IRB ethical guidelines. Thus, we compared reactions to a trauma film paradigm with reactions to a positive film task or cognitive tasks. Overall, relative to other conditions, the trauma film was well-tolerated by participants: they generally reported low-to-moderate negative emotions, moderate benefits, and that participation was not worse than everyday stressors. Our results have implications for the research community in designing trauma-based research.

Introduction

Ethically questionable experiments, such as Little Albert and Zimbardo's Stanford Prison Experiment, plague psychology's history. Unsurprisingly then, psychology researchers sometimes experience difficulties obtaining study approval from IRBs when their research raises concerns about participants' potential distress due to sensitive content (e.g., sexuality, trauma; Jaffe et al., 2015; Yeater et al., 2012). These concerns are inconsistent with the extant

[5] Stirling, N. S. J., Nixon, R. D. V., & Takarangi, M. K. T. (2023). No more than discomfort: The trauma film paradigm meets definitions of minimal-risk research. *Ethics & Behavior, 33*(1), 1-17.

literature; participants typically report low-to-moderate distress—measured variously via the Reactions to Research Participation Questionnaire (i.e., negative emotions, personal benefits, perceived drawbacks, participation factor, and global evaluation; Newman et al., 2001), negative affect, and changes in mood—after participating in trauma research (see meta-analysis: Jaffe et al., 2015, $N = 73{,}959$). However, past research focuses on participants' reactions to answering trauma-related questions. Despite a recent rise in researchers using analogue trauma paradigms (e.g., participants view graphic footage to assess post-traumatic stress symptomology and cognition; James et al., 2016), there is minimal evidence indicating how participant reactions to this type of research fit with ethical guidelines. We also do not know how participants evaluate costs and benefits associated with trauma analogue research. Thus, we examined how participants evaluate their participation experience when exposed to a trauma film paradigm, relative to two other groups: those who watched a positive film, and participants who completed typical cognitive tests.

Despite some variation in global ethics standards for psychological research (e.g., BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018), IRBs converge on concerns regarding the risk of harm to participants. However, how harm is defined is somewhat unclear. In the United States of America's *Public Welfare Act* (2018) and the BPS's *Ethical Guidelines* (2021, p. 10), harm is described within the context of minimal risk research; that is, that the risk and magnitude of harm is no greater than stressors encountered in day-to-day life. BPS guidelines (2021, p.10) include examples of situations that may exceed minimal risk, such as research involving sensitive topics (e.g., people's sexual behaviour), and the induction of psychological stress, anxiety, or humiliation. Australian ethical guidelines, however, provide examples of harms, though acknowledge that the list of harms is not comprehensive (NHMRC, 2018). Within the psychological research context, psychological harm examples include: "…feelings of worthlessness, distress, guilt, anger, or fear related…"

(NHMRC, 2018, p. 13). Examples of discomfort—a step down from harm—include anxiety experienced during an interview and having your blood pressure taken (NHMRC, 2018, p. 13). Therefore, there are variations between countries in how harm is operationalised, though we note that obviously additional definitions of harm exist (i.e., other countries may operationalise harm differently).[6] However, taken together, we can see two common overarching themes between guidelines: (a) the acknowledgement of negative psychological emotions as potential harm, and (b) comparisons of potential harm via participation to everyday stressors.

While researchers report concerns from IRBs regarding trauma-questionnaire research (Jaffe et al., 2015; Yeater et al., 2012), empirical work suggests that participation is typically well-tolerated by participants. For example, distress—e.g., as measured via the Reactions to Research Participation Questionnaire, Profile of Mood States, single distress items, level of interest and confusion questions—is usually low after answering questionnaires on sensitive topics, including childhood sexual victimisation (Edwards et al., 2009), domestic violence (Griffin et al., 2003), and trauma more generally (e.g., natural disasters; DePrince & Freyd, 2006). Participants also report that they would be willing to participate in trauma-related research again (Jaffe et al., 2015). These studies suggest the risk of harm to participants when answering questions about trauma is relatively low.

Globally, IRBs also weigh the benefits of trauma research against potential costs (i.e., risks; BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018). Importantly, participants who answer trauma-based questionnaires report benefits to participating (e.g., gaining personal insight, feeling they contributed to science; DePrince & Chu, 2008; Griffin et al., 2003; Yeater et al., 2012). Moreover, when participants are directly asked to compare benefits and

[6] We chose to focus on these Western countries because this is where the majority of psychological research is currently carried out.

costs of participating, benefits significantly outweigh the costs in trauma-related research (Edwards et al., 2009). Thus, participants do not appear to consider the costs—or risks—of participating in trauma-related research as outweighing the benefits.

Further, past research has examined how answering trauma-questionnaires fits with minimal risk ethics standards by comparing participation to everyday stressors (BPS, 2021; Public Welfare Act, 2018). In one study that directly addressed this comparison, participants reported that answering questions about traumatic experience(s) was no worse than other things in everyday life (DePrince & Freyd, 2006). In a second study, when participants compared answering sex/trauma questionnaires (e.g., childhood sexual victimisation questions) to specific stressors (e.g., getting cavity drilled), they considered stressors worse than participation (Yeater et al., 2012). Together, these studies suggest daily stressors are worse than answering questionnaires about trauma and thus, do not exceed definitions of minimal risk research.

However, the extant literature typically focuses on participant reactions to answering trauma-related questions. In one study that explored participant reactions to negatively-arousing stimuli (e.g., images/sounds; Carter-Visscher et al., 2007)—similar to a trauma-simulation—participation was not considered distressing, and participants were willing to participate again. Thus, perhaps when participants experience an analogue trauma, they too will not experience strong emotional reactions that exceed minimal risk research definitions (BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018). Indeed, although the trauma film paradigm is designed to produce mild reactions in participants that mimic trauma symptoms (e.g., intrusions; James et al., 2016; Oulton et al., 2016), ethically speaking, we as researchers wish to minimise the risk of harm participants to which may be exposed, and thus, ensure that the trauma film paradigm does not meet definitions of harm as described by IRB guidelines (e.g., BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018).

To test whether the trauma film effectively balances this tension between experimental control and ethics—producing a titrated dose of symptoms that does not reach harmful levels—we compared the experience of viewing a trauma film and reporting intrusions about that film (negative experience), with viewing a film of the opposite valence (positive experience), or completing cognitive tasks (control experience). We expected the negative condition, relative to other conditions, to report higher negative emotions and mental costs, and lower positive emotions and perceived benefits. We included a pre- and post-participation mood measure, expecting that—relative to other conditions—the negative condition would report less positive affect and more negative affect over time.

We were also interested in how experiencing an analogue trauma compared to specific daily stressors. We expected that the negative condition would rate participation as more comparable to daily stressors, relative to other conditions, but overall, the negative condition would still report that participation was not worse than the stressors presented.

Method

Participants

One hundred and forty participants completed the research participation measures described here, via Flinders University's SONA system, as part of two broader studies examining memory for analogue emotional events (see Green et al., 2016). Thus, we relied on a convenience sample determined by these studies.[7] Three participants chose to withdraw during the trauma film,[8] thus our final sample was $N = 137$. We conducted sensitivity analyses using G*Power to determine at what effect size(s) we could reliably detect effects

[7] As outlined in Green et al. (2016), exclusion criteria for this study were if participants had previously viewed the film or failed to follow instructions. Here, we retained all participants exposed to the tasks; thus, our final sample was $N = 137$.

[8] We thank the reviewer who drew attention to reasons for withdrawing, which these participants did not disclose. We did not have ethical approval to ask participants this question or to contact them after their participation had concluded. Anecdotally however, participants in our other trauma analogue studies have sometimes spontaneously disclosed that they withdrew because they felt differently—more upset—than they had expected to feel when they read the warning/s (e.g., Bridgland & Takarangi, 2021). Future research using the trauma film paradigm should explore this issue further.

(Perugini et al., 2018). We input: α = .05, 80% power, and our condition sample size. For planned comparisons, we could reliably detect significant effect sizes at d = 0.60 (negative versus control) and d = 0.59 (negative versus positive). For two-way mixed ANOVA analyses, we could reliably detect significant effects at f = 0.13 (η^2 = 0.02). Because ds for significant contrasts were > .59 and η^2 values were > 0.02, these analyses suggest effects are reliable.

Our sample was predominantly female (78.1%), aged 18-43 (M = 21.71, SD = 5.52); 73% identified as Caucasian (including "Australian"); the remainder as Asian (10.9%), European (6.6%), Middle Eastern (2.2%) or other (7.3%; including "Brazilian", "South African", "New Zealander", "Hispanic", "None"). Participants received course credit or compensation (AUD $30). Flinders University's Social and Behavioural Research Ethics Committee granted approval.

Design & Materials

We used a between-subjects design (negative, positive, control).

Negative Condition

To simulate a traumatic experience (James et al., 2016), a third of our participants viewed an 8-minute scene from *The Accused* (1988), depicting a rape (e.g., Lepore, et al., 2004; Takarangi et al., 2017; Takarangi et al., 2014).

Positive Condition

As an emotional contrast to the negative task, participants viewed an 8-minute video depicting Sarah Hughes' 2002 Olympic gold-medal winning performance. Previous research has used the video to elicit positive emotions from participants (e.g., Gruber et al., 2011).

While completing a mundane post-film reading task, participants in the positive and negative conditions reported involuntary film-related thoughts, and answered questions about those thoughts (e.g., phenomenology; further details at: https://osf.io/quk8d/).

Control Condition

To provide a comparison condition to the trauma film paradigm that IRBs would be unlikely to consider potentially harmful to participants—compared to research on sensitive topics (Yeater et al., 2012)—participants completed a typical battery of working memory capacity tasks: Operation Span, Symmetry Span, and Rotation Span (e.g., Unsworth et al., 2009).

Post-Test Reactions Questionnaire (Yeater et al., 2012 ; Appendix A)

To examine participants' retrospective appraisal of participation (i.e., directly after participation), we asked participants to rate their participation experience across four subscales: Negative Emotions (18 items, current study: α = .96; e.g., "This study was emotionally exhausting"), Perceived Benefits (7 items, reverse scored α = .56 e.g., "This study was interesting"), Positive Emotions (6 items, α = .78; e.g., "This study was relaxing"), and Mental Costs (4 items, α = .69; e.g., "This study was mentally exhausting"). All items were rated on a 7-point Likert-type scale, where *-3 = I strongly disagree, 0 = I feel neutral, 3 = I strongly agree.* We included 13 additional statements aligned with common IRB concerns, e.g., "I regret agreeing to participate in this study" (e.g., Carter-Visscher et al., 2007) which we categorised into the above subscales (see https://osf.io/quk8d/).

Normal Life Stressors Scale (Yeater et al., 2012; Appendix B)

Participants compared their participation experience to daily stressors (e.g., "Being late to class"; *-3 = This study was much worse than the event described, 0 = This study was about equally as bad as the event described, 3 = This event described would be much worse than this study*; 38 items; α = 0.99). To examine whether event frequency influenced scores, we included additional high/low frequency stressor items (see https://osf.io/quk8d/).

Positive and Negative Affect Scale (PANAS; Watson et al., 1988; Appendix C)

To capture participant reactions to their research experience over time (i.e., pre- and post-participation), and include a proxy for the negative affect elements that IRBs often refer to in their guidelines (e.g., distress, anxiety), we asked participants to respond to 10 positive (e.g., excited, strong, inspired; $\alpha = .86$ to $\alpha = .90$) and 10 negative (e.g., distressed, afraid, irritable; $\alpha = .84$ to $\alpha = .87$) items (*0 = Very Slightly, 5 = Extremely*).

Procedure

First, participants viewed the consent form, which included warnings regarding the nature of the study: e.g., "Please do not participate in this study if you think that you may be adversely affected by viewing this film, or if for example you have been a victim of sexual or physical violence."[9] If participants chose to proceed (i.e., provided consent), they then completed demographics (i.e., age, gender, and ethnicity) and PANAS questions. Participants randomly assigned to the positive and negative conditions viewed their respective film and completed the post-participation PANAS.[10] Participants assigned to the *control* condition completed working memory tasks at their own pace, then the PANAS. We attempted to match conditions for time, but control participants completed their tasks significantly faster than the other conditions, $F(2, 125) = 7.43$, $p < .001$, $\eta^2 = 0.12$ (negative versus control: $p = .002$, $d = 0.75$, control versus positive: $p = .003$, $d = 0.91$; see https://osf.io/quk8d/).[11]

Next, all participants completed the Post-Test Reactions Questionnaire and Normal Life Stressors Scale. The tasks associated with this study ended, though some participants completed other tasks as part of a different study. We then debriefed participants by informing them about the purpose of the study, as well as providing them with contact

[9] Although previous research shows no difference in intrusive memories for *The Accused* between people with and without an assault history (Salters-Pedneault et al., 2007; 2009), our IRB in 2015-2016 required that we include this warning.
[10] Additional tasks completed here as part of the broader studies: see https://osf.io/quk8d/.
[11] Positive and negative conditions did not significantly differ. Timing data was missing for 10 control participants, which may have contributed to these findings.

information for psychological support services in the event they felt they needed additional support.

Results

Our wider investigation generated additional data (e.g., working memory scores) that we do not analyse here.[12] Although our lab has pre-registered all research since July 2017, the data we report here were collected prior. Nevertheless, the data are publicly available (https://osf.io/quk8d/), and we report how we determined sample size, data exclusions, all manipulations, and all measures in the study.

Research Experience Reactions

We first examined whether viewing a trauma-related film, relative to viewing a positive film, and completing cognitive tasks, influenced participants' research experience across Negative and Positive Emotion, Perceived Benefit, and Mental Cost domains. See Table 3.1 and Figure 3.1.[13] Note, to interpret Figure 1.1, we advise looking to the "agree" and "disagree" anchors for each subscale (i.e., Perceived Benefits, Positive Emotion, Negative Emotion, and Mental Costs). For example, if mean perceived benefit scores are above 0 (i.e., the midpoint), it would mean that on average, participants agreed with perceived benefit items, whereas if mean negative emotion scores are below 0 (i.e., the midpoint), then participants, on average, disagreed with negative emotion statements. We also re-ran all the analyses we report below with our additional Post-Test Reactions Questionnaire items. Because adding these items did not change the pattern of our results (i.e., in terms of interpretation), we have elected to report them in Supplementary Files.

Negative and Positive Emotions

[12] Some of these data are reported in Green et al., 2016.
[13] One participant did not respond to three items on the Post-Test Reactions Questionnaire. We included their data for the other 46 items.

As expected, people who viewed the trauma film (i.e., negative condition) reported significantly higher negative emotions relative to the other conditions. Yet, despite being elevated, negative emotions within the trauma film condition were still in the low-to-moderate range (< 0), suggesting participation did not result in concerning levels of negative emotion. Next, we specifically examined the 17 trauma film condition participants (37.78%) who reported negative mean emotion scores > 0 (the midpoint), because they would arguably be of greatest concern to IRBs given the potential risk of harm posed to them via the trauma film paradigm procedure. In this participant subset, mean negative emotion scores ranged from *M*s = 0.06 – 1.28 (where *3 = I strongly agree* with negative emotion statements). Thus, even among participants reporting the highest negative emotions, these emotions were still only moderate in intensity.

Participants in the trauma film condition, relative to the other conditions, reported lower positive emotion. Overall however, *all* conditions reported low positive emotions post-participation (mean < 0), suggesting that none of the three conditions provided a remarkably positive experience.

Figure 3.1

Comparison of Negative, Control, and Positive Conditions on Mean Post-Test Reactions Scale Scores (with 95% Confidence Intervals)

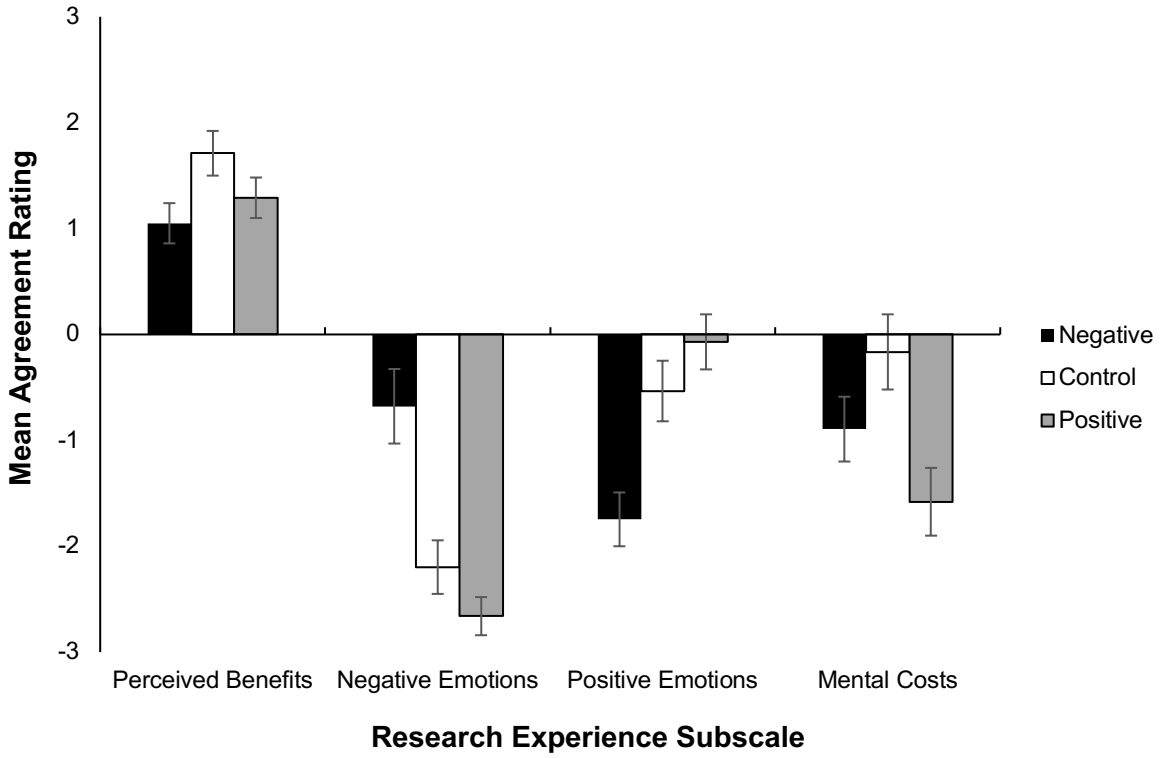


Table 3.1

Planned Comparisons for Condition Type Across Post-Test Reactions Subscales

Comparison	*t(df)*	*p*	*d*	95% CI
Negative Emotions				
Negative vs. Positive	$t(67.12) = 10.00$	< .001	2.11	[1.60, 2.62]
Negative vs. Control	$t(79.80) = -7.02$	< .001	1.49	[1.01, 1.95]
Perceived Benefits				
Negative vs. Positive	$t(91) = -1.83$	.070	0.38	[0.03, 0.80]
Negative vs. Control	$t(87) = 4.86$	< .001	1.03	[0.59, 1.47]
Positive Emotions				
Negative vs. Positive	$t(91) = -9.94$	< .001	2.06	[1.56, 2.57]
Negative vs. Control	$t(87) = 6.79$	< .001	1.45	[0.97, 1.90]
Mental Costs				
Negative vs. Positive	$t(91) = 3.17$	.002	0.64	[0.24, 1.07]
Negative vs. Control	$t(87) = 3.17$	.002	0.67	[0.24, 1.10]

To address our primary research aim, we also examined participants' mood change from pre- to post-participation. In this section we refer to the conditions using identifiable names—for example, trauma film condition (i.e., negative condition)—to avoid confusion with positive and negative affect. We ran two 3 (trauma film, cognitive tasks, Olympic film) x 2 (pre-, post-random allocation) mixed-model ANOVAs on positive and negative affect scores (see Table 3.2).[14] Overall, participants' *positive affect* was higher pre- ($M = 2.62$, $SD = 0.69$) than post-participation ($M = 2.26$, $SD = 0.84$); a significant main effect of time, $F(1,134) = 59.00$, $p < .001$, $\eta^2 = 0.20$. Unsurprisingly, the Olympic film (i.e., positive)

[14] Several PANAS means were negatively skewed. The pattern of results remained unchanged following log and square root transformations, thus we report untransformed data. There were no baseline differences between conditions on positive or negative affect (*ps* = .450 and .663)

condition (M = 2.85, SE = 0.09) had higher positive affect throughout the study than the cognitive task (i.e., control; M = 2.26, SE = 0.09) and trauma film (i.e., negative; M = 2.18, SE = 0.09) conditions; a significant main effect of condition, $F(2, 134) = 15.42$, $p < .001$, $\eta^2 = 0.20$. A significant condition by time interaction ($F(2, 134) = 52.87$, $p = < .001$, $\eta^2 = 0.35$) followed by post-hoc comparisons—with Bonferroni adjustment—showed positive affect was lower in the trauma film condition post-participation than pre-, $p < .001$, $d = 1.17$; we found a similar pattern of results for the cognitive task condition, $p < .001$, $d = 1.18$, where numerically, scores were higher than the trauma film condition. For the Olympic film condition, positive affect was higher post-participation than pre-, $p < .001$, $d = 0.45$.

Turning to *negative affect*, we found that participants' negative affect was lower pre-participation (M = 1.28, SD = 0.36) than post- (M = 1.93, SD = 0.89); a significant main effect of time, $F(1, 134) = 165.98$, $p < .001$, $\eta^2 = 0.41$. Participants in the cognitive task (M = 1.84, SE = 0.07) and trauma film (M = 1.80, SE = 0.07) conditions had higher overall negative affect throughout the study than Olympic film condition participants (M = 1.21, SE = 0.07); a significant main effect of condition, $F(2, 134) = 27.65$, $p < .001$, $\eta^2 = 0.29$. A significant condition by time interaction ($F(2, 134) = 52.69$, $p < .001$, $\eta^2 = 0.26$) and follow-up comparisons—with Bonferroni adjustment—showed that negative affect increased from pre- to post-participation in the trauma film condition, $p < .001$, $d = 1.47$. So did negative affect in the *cognitive task* condition, $p < .001$, $d = 1.82$; numerically, negative affect was slightly higher and greater magnitude (effect size) in the cognitive task condition than in the trauma film condition. There was no pre-post change in negative affect in the Olympic film condition, $p = .406$, $d = 0.20$.

Table 3.2

Descriptive Statistics for the Condition x Time Interaction on Mean Positive and Negative Affect Scores

Condition	Positive Affect		Negative Affect	
	Pre *M (SD)*	Post *M (SD)*	Pre *M (SD)*	Post *M (SD)*
Negative	2.52 (0.63)	1.85 (0.51)	1.31 (0.33)	2.29 (0.88)
Control	2.67 (0.79)	1.86 (0.56)	1.29 (0.35)	2.39 (0.78)
Positive	2.68 (0.70)	3.01 (0.78)	1.24 (0.39)	1.17 (0.30)

Perceived Benefits

Relative to other conditions, the negative condition reported fewer perceived benefits. Yet, the negative condition still reported *moderate* benefits; a one-sided t-test confirmed a significant difference from 0, $t(87) = 4.86$, $p < .001$, $d = 1.03$, 95% CI [0.59, 1.47].

Mental Costs

Contrary to our predictions, control participants reported greater mental costs (i.e., the toll that participants feel it took on them to mentally engage with the research requirements; Yeater et al., 2012) than the negative condition. Hence, completing cognitive tasks was more mentally taxing than viewing an analogue trauma.

Comparison to Daily Stressors

We next considered how viewing a trauma-related film, relative to viewing a positive film, and completing cognitive tasks, compared to everyday stressors.[15] As predicted, the negative condition ($M = 0.86$, $SD = 1.63$) found participation more comparable to everyday stressors (i.e., the scale midpoint of 0 = This study was about equally as bad as the event

[15] Three participants did not answer 1-2 items; unanswered items differed across participants. We included their data for the other 36-37 items.

described), relative to the positive (M = 2.37, SD = 0.67), and control conditions (M = 1.93, SD = 1.24; see Table 3.3), who rated the everyday stressors as being *worse than participation* (i.e., 3 = This event described would be much worse than this study). Notably, negative condition participants did not, on average, report participation was *worse* than the stressor described (i.e., below the scale midpoint). A one-sided t-test confirmed that the negative condition's group mean was significantly above 0 (i.e., the scale midpoint), $t(44) = 3.54$, $p < .001$, $d = 0.53$, 95% CI [0.21, 0.84], hence participation was not necessarily equally as bad as the stressors; instead, participants considered the trauma film *somewhere between* equally as bad (i.e., 0 on the Normal Life Stressors Scale) and not as bad as everyday stressors (i.e., 3 on the Normal Life Stressors Scale). Further, means—by condition for individual items on the Normal Life Stressors Scale—were comparable to Yeater et al. (2012):[16] negative (Ms = -0.67 – 2.73) and control (Ms = 0.77 – 2.82).[17]

Table 3.3

Planned Comparisons Between Negative, Control, and Positive Conditions on Normal Life Stressor Scores

Comparison	$t(df)$	p	d	95% CI
Negative vs. Positive	$t(57.93) = -5.77$	< .001	1.23	[0.78, 1.67]
Negative vs. Control	$t(87) = 3.49$	< .001	0.74	[0.31, 1.17]

Discussion

We investigated whether viewing an analogue trauma film, relative to viewing a film of the opposite valence or completing cognitive tasks, influenced participants' research

[16] Yeater et al. (2012) also included means for their positive condition: Ms = 1.48 – 2.98.
[17] We re-ran these analyses on high and low frequency events but found a similar pattern of results: see https://osf.io/quk8d/.

experience. We also examined how experiencing an analogue trauma compared to specific daily stressors, such as having blood drawn. Though our findings suggested that, relative to the other conditions, viewing a trauma film influenced participant's research experience more so in some regards (e.g., higher negative emotions, lower positive emotions, fewer perceived benefits), overall, we did not find evidence consistent with the idea that viewing an analogue trauma posed significant risk of harm (e.g., distress, anxiety) to participants. We now consider why our findings are more consistent with *discomfort* (e.g., anxiety experienced during an interview) than harm—in accordance with the Australian National Health and Medical Research Council (2018) ethics guidelines—and do not exceed definitions of *minimal risk* research (BPS, 2021; Public Welfare Act, 2018). We also discuss implications for the analogue trauma film paradigm.

First, while negative emotions[18] were higher in the negative condition, overall, negative emotion scores were still low-to-moderate. Even in participants who reported the *highest* negative emotion, the emotion was only of moderate intensity. These findings fit with previous research reporting low participant distress—variously measured via affect (i.e., positive and negative), Reactions to Research Participation Questionnaire, and changes in mood—after answering trauma-related questionnaires (Jaffe et al., 2015; Yeater et al., 2012). The pattern of overall low positive emotion across conditions also aligns with Yeater et al., where participants who answered sex/trauma questionnaires reported overall low positive emotion, relative to participants who completed cognitive tests. However, our finding of *significantly* lower positive emotion for the *negative condition* differed from Yeater et al. Perhaps film modality (negative visual/auditory stimuli) contributed to lower positive

[18] Recall that in the present study, negative emotions represent retrospective appraisals of participation in the study via the Post-Test Reactions Questionnaire (e.g., "This study was emotionally exhausting."). In contrast, negative affect refers to the overall negative feelings participants experienced measured across the study (i.e., pre and post-participation), capturing items such as distress, feeling afraid etc.

emotion, whereas thinking about sensitive topics may not similarly decrease positive emotion.

We also note here that surprisingly, the pattern of PANAS and Post-Test Reactions Questionnaire results differed. Recall for the Post-Test Reactions Questionnaire, negative condition participants reported significantly higher negative emotion and significantly lower positive emotion than control participants. Yet, the negative and control condition participants responded *similarly* across positive and negative affect on the PANAS. This discrepancy may reflect the difference between in the moment evaluations and a retrospective appraisal of participation. A second possibility is that morally people *believe* they should feel worse after watching a rape scene, and appraise their participation accordingly, but their expectation does not translate to *feeling* worse (Anderson et al., 2013). Regardless, the negative condition's retrospective and momentary appraisals of negative emotion were relatively low.

Second, though participants in the negative condition reported fewer perceived benefits than participants in the other conditions, the benefits reported were still *moderate.* This pattern is consistent with previous research (e.g., Jaffe et al., 2015), albeit participants in the current study—within the negative condition—reported slightly lower benefits than those reported for trauma questionnaire research. Thus, despite viewing what IRBs may consider greater than minimal risk research material (i.e., rape film), participants still feel their experience was personally beneficial.

Third, consistent with prior research (Yeater et al., 2012), yet contrary to our prediction, control participants reported greater mental costs than participants in the negative condition. Hence, viewing an analogue trauma was not as mentally taxing as completing a cognitive battery. Perhaps people in the negative condition derived meaning from their experience to cope (Anderson et al., 2013), thus minimising costs. This possibility fits with

the idea participants may accept a higher risk when they experience direct benefits of participating (NHMRC, 2018). Alternatively, perhaps the phrasing of mental cost items reflects cognitive *effort*, rather than emotional costs. Future research could refine these items so they reflect costs relevant to IRBs.

Finally, our findings—consistent with previous research (DePrince & Freyd, 2006; Yeater et al., 2012)—suggest that participants did not perceive viewing an analogue trauma film—depicting a rape scene—as worse than everyday stressors, such as death of a family member or losing an important possession. Our negative condition was slightly lower on stressor scores than Yeater et al.'s sex/trauma condition, perhaps because the analogue trauma film—consisting of visual/auditory stimuli—had more impact on participation experience; this finding is somewhat expected given the trauma film paradigm's aim to provide a mild and temporary dose of symptoms that mimic a trauma response (James et al., 2016). Nevertheless, our participants still found daily stressors as somewhere between being as equally as bad as participation, to the stressors being worse than participation. Given comparisons between participation and daily stressors are used as a proxy to evaluate *minimal risk* research standards (BPS, 2021; Public Welfare Act, 2018), our findings suggest that it is unlikely viewing an analogue trauma film exceeds minimal risk standards.

Implications

Our findings have important implications for the trauma film paradigm; specifically, for films showing third-person rape scenes, such as *The Accused*. Although our data suggest that viewing a trauma film produces no more than discomfort, recall that the aim of the trauma film paradigm is to produce a mild dose of symptoms that mimic reactions to trauma, such as intrusive memories, physiological arousal, negative emotions and cognitions (James et al., 2016). Here, we focused on one of these elements (i.e., negative emotions), because it is the element that most strongly speaks to IRB risk standards. However, it is well-established

that the trauma film paradigm reliably produces intrusions (Chou et al., 2014; Laposa & Rector, 2012; Takarangi et al., 2017), moderate negative emotion (Clark et al., 2015; Holmes & Bourne, 2008), distress (Green et al., 2016; Weidmann et al., 2009), and physiological arousal (Chou et al., 2014; Holmes & Bourne, 2008; James et al., 2016; Schaich et al., 2013). The paradigm has other advantages, too, by allowing researchers to examine traumatic events in an experimentally controlled way—meaning high *internal* validity—where all participants experience the same event for the same duration, with reactions to the event measured after the same interval. However, triangulating methodologies—e.g., by comparing the trauma film paradigm with methods that have high *external* validity, such as participants' reactions to recalling traumatic autobiographical memories—remains critical to understanding PTSD symptomology (Lin et al., 2021). In summary, when coupled with our findings, the trauma film paradigm offers researchers a rigorous way to examine PTS-like symptomology that causes participants no more than discomfort.

Taken together, IRBs consider multiple factors when determining risk, including the potential for *harm* to participants (e.g., psychological harm such as feelings of worthlessness, distress, anger; NHMRC, 2018). Yet second to harm is *discomfort* (e.g., anxiety experienced during an interview; NHMRC, 2018). We argue there are at least four reasons why viewing an analogue trauma film is more consistent with definitions of *discomfort.* First, participants reported low-to-moderate negative emotion, suggesting that viewing the trauma film did not pose a significant risk of harm (NHMRC, 2018). Second, because participants in the negative condition reported moderate benefits and, compared to control participants, fewer costs, we argue that the benefits of viewing a trauma film *outweighed* the costs. Third, the cognitive tasks we used do not have features that should pose risk of harm and thus, seem likely to be approved by IRBs. But, in terms of emotional reaction to participation experience, our negative and control conditions were remarkably similar (i.e., PANAS), suggesting that

viewing an analogue trauma and completing cognitive tasks are comparable experiences. Finally, and of significant note, participants in the negative condition did not indicate participation was worse than daily stressors. Recall that when IRBs evaluate risk of harm—that is, how research fits within minimal risk definitions (BPS, 2021; Public Welfare Act, 2018)—they consider how participation compares to everyday stressors (e.g., death of a close family member, being arrested for a crime I did not commit, having a family member in hospital). Because participants did not, on average, report that viewing *The Accused* was worse than everyday stressors, we suggest that viewing this particular trauma film does not exceed minimal risk research definitions; to do so would mean that participants would need to evaluate their participation experience as worse than everyday stressors, and here, this has not been the case. Perhaps then the level of consideration that may be afforded to—or the perceived risks attached to—trauma-related research is unnecessary. Considered alongside potential trauma research benefits (e.g., improving treatments) and the safeguards used within research (e.g., right to withdraw), our findings suggest viewing an analogue trauma *does not* exceed *minimal risk research* definitions (BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018).

Given past reports of IRB apprehension toward sensitive-based research (Jaffe et al., 2015; Yeater et al., 2012), such apprehension may carry over to research using the trauma-film paradigm because it is designed to induce a mild, temporary, stress reaction in participants. This possibility raises other ethical dilemmas. Participants are considered autonomous agents (NHMRC, 2018); indeed, several participants here exercised their right to withdraw, showing informed consent works in respecting participant's sense of autonomy (NHMRC, 2018). Thus, if IRBs prevent trauma research progression, they may be undermining this right. Moreover, hesitation toward trauma research may generate long-term costs. Advancements in trauma knowledge, including how to treat post-traumatic stress

disorder, could be limited. Given most people have experienced a traumatic event (~ 90% population and ~ 70% of university students; Cusack et al., 2018; Kilpatrick et al., 2013), IRBs must consider the costs of *not* pursuing this type of research.

Limitations

Our study has several limitations. The trauma film we used in this study—which depicts continuous footage of a rape scene via third-person perspective—is only one example of the materials used within analogue trauma research. Previous research uses different types of trauma films, including content such as motor vehicle accidents (Brewin & Saunders, 2001; Strange & Takarangi, 2012), disasters (e.g., fire; Davis & Clark, 1998), and historical events (e.g., the Holocaust; Lepore et al., 2000). Trauma films can also be presented via real-life footage (e.g., motor vehicle accidents; Holmes et al., 2004; Lepore et al., 2000), reconstructions of an event (e.g., Butler et al., 1995), and/or as a compilation of different scenes (e.g., Steil, 1996; Woud et al., 2012). The different films have variable impact (e.g., Arnaudova & Hagenaars, 2017; Weidmann et al., 2009). For example, Weidmann et al. (2009) found that participants reported more immediate intrusions after viewing a rape film clip (i.e., Irreversible, 2003) than natural disaster (i.e., Tsunami) or news report (i.e., Police officers beating protesters, people being badly injured by others etc.) clips. Finally, although most research involves participants passively viewing the materials, some research has provided an analogue (e.g., of a physical assault or haunted house; Cuperus et al., 2017; Dibbets & Schute-Ostermann, 2015) in a virtual reality setting—where a participant wears a head-mounted display that depicts a 3D scene in their environment—or in an interaction environment, where actors portray injuries and nursing students have to treat them (Carleton et al., 2019). Thus, an important next step within this area of literature is to see whether our findings here replicate across other trauma analogue methods.

Second, we did not collect measures of depression, anxiety, or PTSD symptoms. It is possible that the pattern of results we found would differ for people with high symptom levels. For example, perhaps people with higher PTSD symptoms might report higher negative emotion than people with less severe symptoms, after participating in a trauma analogue, as consistent with results from prior trauma-questionnaire research (Jaffe et al., 2015). We also know that PTSD symptoms influence how novel events—which could include a trauma analogue—are experienced and later recalled (Staugaard et al., 2021). Thus, it is important to consider participants' mental health status (e.g., higher levels of depression, PTSD) in planning sensitive research. In research using the trauma film paradigm, some researchers screen out participants indirectly via warnings in the study advertisement and during the informed consent process (e.g., "Please do not participate in this study if you think that you may be adversely affected by viewing this film, or if for example you have been a victim of sexual or physical violence")—as we did here—or, they do so more directly by pre-screening for mental health issues (e.g., Ball & Brewin, 2012; James et al., 2016; Morina et al., 2013; Weidmann et al., 2009). It is also, however, important to balance such screening procedures against collecting data from people who are experiencing, or have experienced, mental health challenges, such as PTS symptoms. For example, offering participants who have experienced a traumatic event—particularly those who may perceive their sense of autonomy was taken from them (e.g., during a sexual assault)—the choice to participate (via informed consent; e.g., NHMRC, 2018) respects participant autonomy. It also avoids researchers encroaching on their decision (i.e., by removing the decision from them via screening measures). Moreover, collecting data from participants who are experiencing mental health challenges is important to inform clinical theory and treatment, which may in turn offer benefits to the wider community (e.g., by improving treatment for other people).

Taken together, the most appropriate method of screening likely depends on the aims of individual studies as well as individual IRB requirements.

Third, and somewhat relatedly, we did not assess participants' trauma history (i.e., sexual assault) and how it may have influenced participants' experience in viewing a rape scene. This is an important consideration for several reasons. First, our sample was 78.1% women and we know women have higher rates of experiencing a sexual assault than men (e.g., Mellins et al., 2017). Second, maintaining participants' wellbeing and safety is a research priority, regardless of the aims of the study. Yet, doing so is not always as simple as screening out particular participants, as we have noted. Providing participants who may have a similar trauma history to the film with a choice to participate—thus respecting their sense of autonomy (BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018)—is also an important consideration. Moreover, previous research indicates that participants with a history of sexual assault who view a similar analogue trauma of a rape show no difference in emotional reactivity to those without this history (Bridgland & Takarangi, 2021; Salters-Pedneault et al., 2007; Salters-Pedneault et al., 2009), therefore we would not predict differences. Nevertheless, we urge researchers to continue examining these important ethical issues in research design.

Fourth, we only measured participation reactions over ~30 minutes. Importantly, when IRBs consider the risk of harm to participants, it is not only about what happens during the in-lab session, but also the potential impact on participants over time (e.g., NHMRC, 2018; Public Welfare Act, 2018). Hence, a limitation to our design is that we do not know how participants felt about their participation after a longer duration (e.g., 1-week, 1-month). However, past research using analogue trauma finds decreases in analogue trauma symptoms, such as intrusive memories and reported distress, 24 hrs (Oulton et al., 2018), 4 days (Rattel et al., 2019), and 7 days post exposure (Schultebraucks et al., 2019); thus, we might expect

we would find a similar pattern when measuring participation reactions to the trauma film over longer time periods. Nevertheless, future research should directly address this important issue.

Fifth, the control condition completed tasks quicker than other conditions; however, if the control condition spent more time on tasks, their mental cost and negative emotion scores may have paralleled the negative condition. The negative and positive conditions also completed intrusion-related tasks that may have influenced results. Yet measuring intrusions is often part of analogue trauma paradigms (e.g., James et al., 2016), and thus represents real-world investigations into trauma.

Sixth, as part of our consent process, we included warnings during consent about the potentially distressing nature of the film. These warnings may have inadvertently created negative expectations about viewing the film (e.g., the film will result in feelings of distress) that made those reactions more likely (i.e., *nocebo effects;* Barsky et al., 2002). However, all participants read the same warning and did not know which condition they would be randomly allocated to, which may have ameliorated some of these expectations.

Finally, we examined first-year university students, thus results may not generalise. Nevertheless, university and non-university trauma samples are comparable across factors such as avoidance coping, associations between PTSD symptoms and event centrality, and physiological reactions (Boals et al., 2020).

Conclusion

Our data provide preliminary evidence that viewing an analogue trauma is well-tolerated by participants. Therefore, research using trauma analogue films—specifically those portraying a third-person rape scene such as *The Accused*—with certain ethical parameters in place (e.g., alongside informed consent, confidentiality, debriefing) can be informative without exceeding minimal risk definitions of research (BPS, 2021; Public Welfare Act,

2018). We hope our data can be of use to researchers and IRBs in shaping future trauma-based studies.

Supplementary Files

Table S1

Means and Standard Deviations for Post-Test Reactions Subscales (Yeater et al., 2012)

Subscales	Condition		
	Negative *M (SD)*	Control *M (SD)*	Positive *M (SD)*
Negative Emotions	-0.68 (1.17)	-2.20 (0.84)	-2.66 (0.64)
Perceived Benefits	1.05 (0.63)	1.71 (0.65)	1.30 (0.71)
Positive Emotions	-1.75 (0.74)	-0.53 (0.93)	-0.07 (0.87)
Mental Costs	-0.89 (0.99)	-0.16 (1.18)	-1.58 (1.23)

Table S2

Descriptive Statistics for the Condition x Time Interaction on Positive and Negative Affect Scores

Condition	Positive Affect		Negative Affect	
	Pre *M (SD)*	Post *M (SD)*	Pre *M (SD)*	Post *M (SD)*
Negative	25.16 (6.27)	18.51 (5.09)	13.09 (3.33)	22.90 (8.78)
Control	26.66 (7.85)	18.61 (5.60)	12.91 (3.52)	23.86 (7.77)
Positive	26.83 (6.66)	30.10 (7.82)	12.44 (3.86)	11.71 (3.01)

Note. Analyses revealed no baseline differences in positive or negative affect (*ps:* .450 and .663). The pattern of results (i.e., significance) remained consistent between total PANAS and mean PANAS scores.

Table S3

Planned Comparisons for Condition Type Across Post-Test Reactions Subscales (All Items)

Comparison	*t(df)*	*p*	*d*	95% CI
Negative Emotions				
Negative vs. Positive	*t*(65.10) = 9.78	< .001	2.07	[1.56, 2.57]
Negative vs. Control	*t*(78.92) = -6.86	< .001	1.49	[0.98, 1.91]
Perceived Benefits				
Negative vs. Positive	*t*(91) = -3.23	.002	0.67	[0.25, 1.09]
Negative vs. Control	*t*(87) = 4.78	< .001	1.01	[0.57, 1.45]
Positive Emotions				
Negative vs. Positive	*t*(91) = -9.95	< .001	2.06	[1.56, 2.57]
Negative vs. Control	*t*(87) = 6.79	< .001	1.43	[0.97, 1.90]
Mental Costs				
Negative vs. Positive	*t*(91) = 3.17	.002	0.66	[0.24, 1.07]
Negative vs. Control	*t*(87) = 3.17	.002	0.67	[0.24, 1.10]

We also re-ran all analyses using the additional Post-Test Reaction items that we added to Yeater et al.'s (2012) existing items. The addition of these items only changed the pattern of results for the negative versus positive condition comparison on perceived benefit scores; that is, the previous analysis was nonsignificant and the addition of eight perceived benefit items (e.g., "I found participating to be personally meaningful") led to the positive condition being significantly higher in perceived benefits than the negative condition, $t(91) = -3.23$, $p = .002$, $d = 0.72$.

Upon closer inspection of the additional perceived benefit items, it became apparent that two items, "This study made me think about things I didn't want to think about (item 30)" and "I think I will experience distress in the future as a result of participating in this

study (item 32)", significantly differed in their means [item 30: $t(91) = -7.79$, $p < .001$, $d = 1.63$, item 32: $t(48.86) = -5.71$, $p < .001$, $d = 1.03$]. Given these items are arguably not entirely relevant to the positive condition, it is perhaps unsurprising that the conditions differed, the overall significant difference between condition on perceived benefits is likely due to these specific items.

Results for Participants Reporting the Highest Negative Emotion

We re-ran descriptive statistics on the Normal Life Stressors Scale (i.e., comparison to everyday stressors) for the 17 participants who reported the highest levels of negative emotions. Of these 17 participants, 52.9% (i.e., 9 participants) indicated that participation was as bad as everyday stressors (*Ms:* 0.29 to 2.92), while 47.1% (i.e., 8 participants) reported that participation was worse than the everyday stressors (*Ms:* – 0.33 to -2.67). We also re-ran analyses for these participants on positive emotion, perceived benefits, and mental costs. We found that 88.2% (i.e., 15 participants) reported low positive emotion (*Ms:* -0.33 to – 2.67) and 11.8% (i.e., 2 participants) reported moderate positive emotion (*Ms:* 0.17); 70.6% (i.e., 12 participants) reported low mental costs (*Ms:* -1.75 to -0.25), while 29.4% (i.e., 5 participants) reported moderate mental costs (*Ms:* 0.25 to 1.25); and 100% (i.e., 17 participants) reported moderate to high perceived benefits (*Ms:* 0.14 – 2.86).

Chapter 4: Research Question Two: Do Participants—Including Trauma-Exposed Participants—Have Unique Ethical Requirements, Beyond Current Ethical Guidelines, for Participation in Trauma-Related Research?

Recall that some researchers and IRBs question whether trauma-exposed people who participate in trauma-related research are particularly vulnerable to harm (e.g., Carter-Visscher et al., 2007; Newman et al., 2006). "Trauma-exposed" here refers to people who have been exposed to a traumatic event in line with Criterion A definitions for a PTSD diagnosis (DSM-5; APA, 2013). There are several reasons for this vulnerability concern, including fears about "retraumatisation" (e.g., Jaffe et al., 2015; Weiss, 2021), existing PTSD-like symptomology worsening (e.g., Newman et al., 2006), or that trauma-exposed participants may have impaired decision-making capacity to consent (e.g., Newman & Kaloupek, 2009).[19]

Such concern begs the question: should trauma-exposed people who participate in trauma-related research require unique and additional ethical precautions? Should this group be considered similar to other vulnerable populations identified within ethical guidelines (see Newman & Kaloupek, 2009 for discussion)? For instance, the US and Australian guidelines highlight universally vulnerable people (National Commission, 1979), such as children and prisoners, as people who may be susceptible to undue influence (NHMRC, 2018; Public Welfare Act, 2018). These guidelines subsequently include broad recommendations, such as directing vulnerable participants to discuss consent with someone else to help them make an informed and voluntary decision (e.g., NHMRC, 2023). However, one difficulty with vulnerable populations in ethical guidelines, as Newman and Kaloupek (2009) highlight, is that such guidelines rarely identify who comprises vulnerable populations and/or outline

[19] We also note concern that participants who have experienced, or are still experiencing, certain traumatic events (e.g., intimate partner violence) may be more susceptible to coercion during the informed consent process (e.g., Newman & Kaloupek, 2009). While this is an important point to consider, is it beyond the scope of my thesis (see Fontes, 2004 for a nuanced discussion).

specific precautions for different populations. Thus, there is no easy answer to whether trauma-exposed participants fit within the vulnerable population category.

Certainly, some existing literature has examined ethical issues attached to psychological trauma-related research, like reactions to participation (see Chapter 2). Related work provides commentary on these ethical issues, for example, developing and applying a trauma-informed framework to sexual violence research and/or open science practices (Campbell et al., 2019). However, this existing literature comes primarily from *researchers'* perspective (e.g., Newman et al., 2006), and does not directly ask participants to evaluate current ethical protocols. For instance, do trauma-exposed participants believe they need additional considerations—possibly rising to the ethically vulnerable population level—or do they have alternative preferences?

Here, I will focus only on feedback related to the *informed consent process*. Aside from reasons of scope, informed consent processes directly relate to communicating possible harms—or risks—to participants. Indeed, potentially inaccurate risk assessments IRBs make about trauma-related research may be communicated to participants via consent risk information (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Carter-Visscher et al., 2007). In fact, trauma researchers have previously reported that some IRBs mandate specific risk communication wording (e.g., Cromer et al., 2006). In one example, for participants responding to trauma-related questions, the researchers were required to inform participants that they may feel distressed, and if so, to contact a listed researcher who was available 24-hours a day (Newman et al., 1999). Thus, it would be useful for researchers and IRBs to receive feedback from trauma-exposed participants on informed consent processes.

Below, I consider literature about informed consent challenges in research considering human subjects *generally,* across different perspectives (e.g., researchers, IRB

members). Note that some prior research assesses the participant's perspective on informed consent challenges.

Perspectives About Informed Consent Issues in Research with Human Subjects

Institutional Review Board Perspectives

Prior and/or current IRB members provide one perspective on informed consent challenges. This previous research has gathered IRB input about practical challenges of informed consent, such as translating documents into other languages (e.g., Klitzman, 2014), and general feedback about informed consent (e.g., Klitzman, 2013), including whether participants can understand consent forms (e.g., is the form too complex; Kane & Gallo, 2017). Some IRBs and their associated delegates have published guidelines for other IRBs and researchers about how to improve the informed consent review process, both in how researchers write consent documents and how IRBs review such documents for comprehensibility (Davies, 2022). Several studies evaluate how IRBs operate (e.g., Abbott & Grady, 2011; Robertson, 1982), including common feedback IRBs provide to researchers about informed consent (e.g., "word clarity"; Blackwood et al., 2015). Specific to a medical-based context, other research has gathered, and subsequently compared, perspectives from prior IRB members and patients on informed consent (Kraft et al., 2016). Notably, Kraft and colleagues (2016) found that patients—i.e., key stakeholders in the consent process—differed from IRBs on several consent points, such as who (e.g., patient's clinician, research staff member) should obtain consent. Given such differences in views between IRBs and patients, Kraft et al.'s findings suggest it is important to assess participants' views and preferences about informed consent practices.

Researcher Perspectives

Researchers provide a second perspective on informed consent in research with human subjects. Some studies have used qualitative approaches (e.g., semi-structured

interviews or focus groups) to investigate researchers' experiences and views on informed consent, such as obtaining consent from participants (Wiles et al., 2007; Xu et al., 2020); determining what information should be included during the consent process (e.g., Rivera et al., 2007); communicating risks and benefits to participants (Nusbaum et al., 2017); training others in the consent process (Nusbaum et al., 2017); and delivering consent across international research teams that differ in their approach to informed consent (e.g., Dawson & Kass, 2005; Sabik et al., 2005). Furthermore, researchers have measured participants' informed consent comprehension (e.g., Bergenmar et al., 2008; Chaisson et al., 2011; Tam et al., 2015). With the aim to improve comprehension, researchers have also empirically tested (e.g., altering detail included at consent) changes to consent (see Dunn & Jeste, 2001 and Nishimura et al., 2013 for reviews). Together, this prior literature represents and acknowledges researcher perspectives about the informed consent process.

Participant Perspectives

A few studies have examined *participant* views about informed consent (e.g., Pope et al., 2003). For instance, Anderson and colleagues (2017) conducted focus groups—with people who had previously participated in research—to investigate experiences with informed consent. Participants generally reported positive experiences with the informed consent process (e.g., trusting researchers), but cited difficulties with the consent information itself, such as the documents being too long or difficult to understand. Similarly, O'Sullivan and colleagues (2021) examined how participants and research staff evaluated informed consent in medical-based research. Participants typically reported positive prior informed consent experiences (e.g., when they were approached to participate, information provided), and offered two key pieces of feedback: ensure there is sufficient time to conduct the informed consent process and provide more follow-up post-participation. In an additional example, The Advisory Committee of Human Radiation Experiments—based in the US—

interviewed participants from prior research studies to investigate their experiences and attitudes toward research (Sugarman & Kass, 1996). Notably, this investigation found that participant *trust* was integral: participants reported that trust in their physician and subsequent referral to participate in research, and trust in the relevant institution (e.g., hospital, university) contributed to their decision to participate.

In a further example, Cook and Hoas (2011) investigated participant views on informed consent, including what information they would prefer to see included and participants' decision-making process (e.g., factors affecting the decision to participate). While most participants indicated they had read the consent form—with adequate time to do so—most participants did not remember critical consent information (e.g., related to confidentiality). However, they requested more information about the commercial purpose of the research and researcher/institution compensation. Several factors influenced participants' decision to participate: first, general factors such as people's illness status, altruism, or that they would benefit financially; second, who recruited them (i.e., 46% of people reported their doctor or healthcare providers recommended they participate versus 6% of people who reported they participated to obtain course credit), and, relatedly, whether people had a trusting relationship established with the people who recruited them; and third, people's ability to withdraw after beginning participation, with some participants reporting they felt they could not withdraw because they would be "letting the researchers down".

A small body of this research also considers participant perspectives about the *unique* challenges in research involving biobanks and genetic information (e.g., re-consent practices for large-scale population-based genomic studies; e.g., D'Abramo et al., 2015; Goodman et al., 2016).

Summary

Together, several perspectives on informed consent in research with human subjects are available in the literature (i.e., prior and current IRB members, researchers, participants). These studies point to complexity in examining ethical issues related to informed consent. For example, different stakeholders may have alternative, and at times opposing, views on informed consent practices. But there is a need to balance input from multiple stakeholders. For instance, bringing the focus back to a psychological trauma-related context, while some IRBs mandate harsher consent risk information for trauma-related research to protect participants, trauma-exposed participants might feel differently about this practice. Next, I will review literature on perspectives specific to psychological research and psychological *trauma-related* research.

Perspectives About Informed Consent Issues in *Psychological* Research

Researcher Perspectives

Most existing literature that considers informed consent issues in psychological research specifically occurs from *researchers'* perspectives. One research area considers whether, and to what extent, people read informed consent forms. Overwhelmingly, prior experimental work indicates that undergraduate research participants either do not read or otherwise skim informed consent forms (e.g., Douglas et al., 2021; Geier et al., 2021), with estimates ranging from 5% to 47.3% of participants who report not reading the form, and between 30% to 69% who report skim reading the form (Perrault & Keating, 2018; Perrault & Nazione, 2016; Varnhagen et al., 2005). Moreover, when researchers measure participants' consent form comprehension—via a free recall test, open-text response questions, or multiple-choice questions—participants show low-to-moderate comprehension (e.g., Perrault & Keating, 2018), typically getting less than half the comprehension questions correct (Pedersen et al., 2011; Perrault & Nazione, 2016; Varnhagen et al., 2005).

Relatedly, researchers have assessed participants' attitudes toward informed consent practices to understand why they generally do not read/skim consent information (e.g., Perrault & Keating, 2018; Perrault & Nazione, 2016). Overall, there are several consistent and/or similar reasons for this behaviour, including that: consent forms seem similar between studies, the form was too long or contained too many words, the participant knew the university department was required to follow ethical guidelines, it did not seem important, or the participant did not realise it was a consent form (Geier et al., 2021; Perrault & Keating, 2018; Varnhagen et al., 2005).

Consequently, another related research area examines how to *improve* people's informed consent form comprehension. One approach researchers have taken is to randomly allocate participants to view different consent form versions (e.g., one consent form has important information bolded, another consent form present information using bullet-points), then measure participants' comprehension (Geier et al., 2021; Mann, 1994; Perrault & Keating, 2018; Perrault & Nazione, 2016; Varnhagen et al., 2005), or even measure participants' behaviour using eye-tracking between consent forms varying in length (Rosa et al., 2019). Such research has *directly* asked participants for feedback that would improve the consent process (e.g., Geier et al., 2021; Perrault & McCullock, 2019; Perrault & Nazione, 2016). Participant feedback has included: shortening forms, including fewer words, bolding or underlining important information (i.e., to bring participant's attention toward it), altering the consent information format (e.g., using bullet points; Geier et al., 2021; Perrault & Keating, 2018); making forms more engaging (e.g., by including pictures or incentivising people to read them (e.g., by testing them on the content; Varnhagen et al., 2005); or using an abbreviated consent process where participants could access more detailed information if interested (Perrault & McCullock, 2019). Notably, this body of research has examined

ethically neutral research, such as people's personality traits, rather than psychologically sensitive research areas where risks may be more prominent.

Finally, there are several published reviews and commentaries about researcher concerns (e.g., consent research not examining how people interact with the consent process) over the informed consent process (e.g., Mumford, 2018; Gupta & Kharawala, 2012). Together, this research not only highlights *researcher* perspectives on psychological research consent issues, but also, how important it is to consider participant feedback and preferences in improving consent procedures.

Participant Perspectives

To the best of my knowledge, there is only one qualitative study on participants' experience with the informed consent process for psychological research. Brody and colleagues (1997) interviewed 65 undergraduate participants who reported previously participating in various studies (e.g., reaction time and memory, decision-making tasks, mood induction). In line with research on human subjects more generally (e.g., Anderson et al., 2017), most (79%) participants reported positive informed consent experiences, for reasons such as feeling they had received adequate information about the study. Participants reporting negative experiences cited reasons such as the study being too invasive (e.g., researchers requested more personal information than anticipated), or that the information they received via informed consent was insufficient. The researchers concluded that many participants reported a positive consent experience despite not understanding consent's purpose; only around 20% of their sample viewed the informed consent process as a decision-point. Importantly, this study was not focused on sensitive research, or participants with prior trauma-exposure, and did not *directly* ask participants to evaluate or provide their preferences for consent guidelines.

Perspectives About Informed Consent Issues in Psychological *Trauma* Research

Researcher Perspectives

Turning next to psychological trauma-related research specifically, again most occurs from *researchers'* perspectives. Some researchers have published commentaries (Becker-Blease & Freyd, 2006; Campbell et al., 2019), and narrative (Newman & Kaloupek, 2009; Newman et al., 2006), systematic (Jorm et al., 2007), or meta-analytic (Jaffe et al., 2015), reviews about the broader ethical issues facing psychological trauma-related research, including challenges to informed consent. Other researchers have examined informed consent content (Abu-Rus et al., 2019), or have considered how participant reactions to answering trauma-related questionnaires fit with informed consent procedures and ideas about participant vulnerability (e.g., Jaffe et al., 2015; see also Chapter 2 for relevant literature review).

Participant Perspectives

Some studies within the psychological trauma-related research participation literature consider participants' experiences with participation, including informed consent (e.g., Edwards et al., 2009). For example, several studies use the Reactions to Research Participation Questionnaire, which allows participants to provide direct feedback on their participation experience (e.g., by responding to statements such as "I found participating in this study personally meaningful"; e.g., DePrince & Chu, 2008) and includes specific items related to the consent process such as, "I understood the consent form" (Global Evaluations domain), "Participation was a choice I freely made" (Participation domain), and "I felt I could stop anytime" (Participation domain; Newman & Sinclair, 2001). However, these studies assess consent attached to their specific study and only indirectly examine how trauma-exposed participants evaluate consent; they do not offer a format for more general feedback relating to participants' evaluations and preferences for consent. Therefore, while it

may be possible to infer what participants, particularly trauma-exposed participants, want regarding the informed consent process, minimal-to-no prior research has made significant effort to understand trauma-exposed and non-trauma-exposed people's direct evaluations of, and preferences for, informed consent.

Together, prior literature documents IRB, researcher, and to a smaller degree, participant perspectives about consent procedures for research with human subjects generally. Similarly, psychological literature, including trauma-specific research, mostly occurs from researchers' perspectives. It is therefore unclear how *participants*—who may comprise an ethically vulnerable population—think about current informed consent procedures. Are these guidelines serving them as intended or do participants have unique preferences for consent guidelines? Do trauma-exposed and non-trauma-exposed participants require different consent procedures? Do trauma-exposed participants' responses to these questions suggest they should be classed as an ethically vulnerable population? The answers to these questions are, at present, unclear. Thus, my thesis' second aim is to "hear" trauma-exposed and non-trauma-exposed participants' voices (i.e., views, knowledge, and preferences) for informed consent guidelines currently used in psychological trauma-related research.

Chapter 5: The participant's voice: Crowdsourced and undergraduate participants' views toward ethics consent guidelines[20]

Author contributions: I developed the study design, collected and cleaned the data, and performed the data analysis and interpretation. OM coded data alongside myself for the purposes of interrater reliability. I drafted the manuscript and MKTT provided critical revisions. MKTT approved the final version of the manuscript for submission.

Abstract

The informed consent process presents challenges for psychological trauma research (e.g., IRB apprehension). While previous research documents researcher and IRB-member perspectives on these challenges, *participant* views remain absent. Thus, using a mixed-methods approach, we investigated participant views on consent guidelines in two convenience samples: crowdsourced ($N = 268$) and undergraduate ($N = 265$) participants. We also examined whether trauma-exposure influenced participant views. Overall, participants were satisfied with current guidelines, providing minor feedback and ethical reminders for researchers. Moreover, participant views for consent were similar irrespective of trauma-exposure. Our study has implications for IRBs and psychological researchers.

Introduction

As researchers and clinicians within psychology, we know the importance of informed consent practices. Such practices aim to show *respect* toward participants as individuals and maintain their sense of *autonomy*; it is critical that participants can make an educated and voluntary decision about whether research participation is suitable for them (BPS 2021; NHMRC, 2018). However, the informed consent process presents several challenges to psychological researchers (e.g., Burgess, 2007). For instance, we know that

[20] Stirling, N. S. J. & Takarangi, M. K. T. (2024). The participant's voice: Crowdsourced and undergraduate participants' views toward ethics consent guidelines. *Ethics & Behavior.* Advance online publication.

participants seldom read consent forms (e.g., Perrault & Nazione, 2016; Ripley et al., 2018), leading to issues with comprehension (e.g., Geier et al., 2021; Mann, 1994; Perrault & McCullock, 2019;), and uncertainty about whether participants are truly "informed" (e.g., Varnhagen et al., 2005). Consider then psychologically sensitive areas of research, like trauma research, where additional consent-related challenges exist because of IRB concerns (e.g., Jaffe et al., 2015; Newman et al., 2006). For example, IRBs may mandate more severe risk information in consent forms than is clinically indicated—potentially leading to over-warning participants—or may question whether research with trauma-exposed populations (i.e., people who have experienced a traumatic event) should even occur (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Newman & Risch, 2006; Yeater & Miller, 2014). To address such challenges, researchers have examined how people react to participation in trauma-related research (Carlson et al., 2003; Jaffe et al., 2015; Legerski & Bunnell, 2010), provided recommendations to improve ethical guidelines (e.g., using a trauma-informed approach; Campbell et al., 2019; Cook & Hoas, 2011), and gathered feedback generally from IRBs (e.g., Rothstein & Phuong, 2007). Yet what remains absent is *participants' views* on current ethical processes, including consent processes. Thus, we aimed to address this overarching issue here, alongside our secondary interest in whether participant preferences for consent differ based on their prior exposure to a traumatic event. Hereon we refer to trauma-exposed and non-trauma-exposed participants in line with Criterion A for a PTSD diagnosis in the DSM-5 (APA 2013; Newman & Kaloupek, 2009).

One concern that some IRBs and researchers have is that trauma-related research—i.e., research involving participants who have experienced traumatic events, that asks participants about those events, and/or that involves exposing participants to analogue trauma—is riskier than other types of psychological research (see Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Cromer et al., 2006; DePrince & Freyd, 2006; Mathews et al.,

2022; Newman et al., 2006; Yeater & Miller, 2014 for discussion), because it might cause—or further worsen existing—psychological harm (e.g., Jaffe et al., 2015; Newman et al., 2006). Indeed, previous research has documented fears that this type of research may increase participants' negative mood, retraumatise them, and/or worsen their PTS symptoms, possibly leading to psychologically "shattering" participants (Cromer et al., 2006; Jaffe et al., 2015, p. 41; Newman, 2008; Newman et al., 2006). A second concern is whether participants—particularly those who are trauma-exposed—are even able to make an informed decision to participate in trauma-related research, (Becker-Blease & Freyd, 2006; Du Mont & Stermac, 1996; Newman & Kaloupek, 2009; Newman et al., 2006; see also Fontes, 2004 for a nuanced discussion about people experiencing intimate partner violence, which is beyond the scope of the current paper). At the most extreme, people who participate in trauma-related research are considered a vulnerable population, in line with populations inherently afforded special ethical precautions, including children (e.g., Newman & Kaloupek, 2009; Newman et al., 2006; Yeater & Miller, 2014).

Yet, a growing body of literature suggests that these concerns about trauma-related research are unfounded. First, the risk to participants in trauma-related research may *not* be greater than for other types of psychological research (e.g., Jorm et al., 2007; Yeater & Miller, 2014). For example, in Cromer and colleagues' (2006) first study, participants reported no significant difference in distress after answering questions about emotional and sexual abuse, relative to questions about body image and SAT/GPA scores. Other researchers have found likewise: participants who answered questionnaires related to trauma and sexual experiences, and participants who completed cognitive exercises (e.g., IQ tests) reported similarly low levels of negative emotion during participation (Yeater et al., 2012). In fact, most research indicates participants tolerate trauma-related research: many participants report low-to-moderate distress and moderate-to-high benefits (see meta-analysis of $N = 73{,}959$ by

Jaffe et al., 2015). Even participants with PTSD or prior trauma-exposure who report somewhat elevated distress also report significant benefits to the research, alongside little-to-no regret regarding participation (Jaffe et al., 2015; Mathews et al., 2022; Newman & Kaloupek, 2009). In fact, these participants typically report research benefits outweigh costs to participation (Edwards et al., 2009; Kassam-Adams & Newman, 2005; McClinton Appollis et al., 2015; Newman & Kaloupek, 2009).

Second, experts within the field generally agree—despite suggestions from some IRBs—that trauma-exposed participants have the *capacity* to make an informed decision regarding participation; that is, trauma-exposure does not impair a person's ability to make such decisions (Collogan et al., 2004; DePrince & Chu, 2008; Hebenstreit & DePrince, 2012; Newman & Kaloupek, 2009; Newman et al., 2006; Ruzek & Zatzick, 2000). Indeed, prior research finds that participant coercion—partially operationalised via participant's understanding of the consent form—is minimally indicated and *unrelated* to PTSD status (Jaffe et al., 2015). In summary, extant research suggests there is no inherent need to treat people with prior trauma-exposure as an ethically defined vulnerable population.

Existing literature on ethical issues in research has mostly collected researcher, past IRB member, and ethicist perspectives. For instance, prior literature documents how participants react to trauma-related research (e.g., Jaffe et al., 2015) and researchers' experiences with participants and consent (Xu et al., 2020). Moreover, extant literature reports IRB member perspectives, such as the importance they place on different ethical issues arising in ethics applications (e.g., informing participants about risks; Allison et al., 2018; Rothstein & Phuong, 2007). Several prior papers also feature researcher and/or ethicist commentary on ethical issues in consent (e.g., Becker-Blease & Freyd, 2006; Haverkamp, 2005; Wells & Kaptchuk, 2012), such as applying a trauma-informed care perspective to ethical guidelines (Campbell et al., 2019).

The limited literature that examines what *participants* think of *consent* has done so with researcher/IRB intent. For instance, researchers have asked participants how to improve consent forms (e.g., bolding information), with the purpose of increasing consent form readability (e.g., Perrault & Keating, 2018; Perrault & Nazione, 2016). Similar research investigates why participants choose not to read and/or skim consent forms (e.g., Douglas et al., 2021; Geier et al., 2021; Perrault & Nazione, 2016), highlighting personal characteristics—like "pure laziness"—as a possible explanation (Perrault & Keating, 2018). Other research has focused on participant expectations within the researcher-participant relationship (e.g., participant's obligations to the researcher, such as cooperation; Epstein et al., 1973; Singer, 1984) or on participants' decision-making process during consent (e.g., when do people make the decision to consent to participate), including what specific consent information participants want (Cook & Hoas, 2011); though we note the latter study was not specific to the psychological trauma-related research context.

Taken together, extant literature provides evidence and expert opinions from researchers, prior IRB members, and ethicists regarding ethical issues within psychological research, including consent issues in trauma-related research. We also have some understanding of what participants think of specific ethical considerations, including consent form presentation. But we do not know how *participants*—arguably the key stakeholders—evaluate ethical consent guidelines and practices. Another way to think about this issue is: are the recommendations based on current guidelines (e.g., from BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018) and empirical evidence that we use what participants want for consent? At a basic level, are participants aware (i.e., knowledgeable) of the consent information they should currently receive? Essentially, how well are current guidelines currently serving participants? Here, to address these questions, we examined participants' general understanding (i.e., knowledge) of, and expectations (i.e., preferences) for, consent

practices. Across two studies, we sampled two commonly used samples: US crowdsourced and Australian undergraduate participants.[21] Given some IRB apprehension toward trauma-related research, including trauma-exposed participants (e.g., Newman et al., 2006), we had a secondary interest in whether trauma-exposed participants differed from non-trauma-exposed participants in their consent views and preferences. Finally, we had a broader interest in understanding our commonly used sample types (e.g., prior study completion experience, why they choose to participate).

Study 2a

Method

The Flinders Human Research Ethics Committee (4759) approved this study. We report all measures, conditions, and data exclusions. We pre-registered this study (https://osf.io/gjryt), as well as Study 2b (https://osf.io/undxz); the data files and all available supplementary files are available at: Study 2a: https://osf.io/gnwq4/; Study 2b: https://osf.io/ru8e5/.

Participants

Because correlations stabilise as they approach $N = 260$ (Schönbrodt & Perugini, 2013; 2018), we aimed to collect 260 participants. We based this decision on wanting to run internal consistency analyses since many of the questionnaires used here were created specifically for our study.

Using Amazon's Mechanical Turk (MTurk), we collected 272 participants. In line with our pre-registered exclusion criteria, we excluded three participants for responding incorrectly to the cultural check question and one participant for failing all three attention

[21] We chose these samples because they are frequently used within psychological research (e.g., Luong & Lomanowska, 2022; Strickland & Stoops, 2019) and thus, would likely provide valuable insight into consent views for these populations (i.e., we could generalise our findings to these samples). These are also the convenience samples we had access to, given US crowdsourced participants are typically easier to source than Australian crowdsourced participants.

checks (see Moeck et al., 2022); we also excluded one participant because they submitted inappropriate open-ended responses (i.e., containing extensive profanity that did not answer our survey questions) that rendered their data unusable. Thus, our final sample of 268 participants were 56.3% women (men: 42.5%, non-binary: 0.4%, prefer not to say: 0.7%), aged 19 - 76 (M = 39.91, SD = 11.68). Most participants were Caucasian (67%; Black: 12.4%, Mixed: 6%, Asian: 4.9%, Hispanic: 4.1%, Filipino: 1.5%, Native American: 1.1%, Latino: 0.7%, and Italian, Middle Eastern, Other [e.g., "unknown"], Caribbean, African, Chinese: 0.4%, respectively). Their highest level of education was most often a bachelor's degree (44.8%; high school/equivalent: 23.9%, associate degree/diploma or certificate: 19.4%, master's degree: 9.7%, doctoral studies: 1.5%, and primary school: 0.7%). On average, participants reported having completed 14,055.7 (SD = 32,237.30; median = 5,000 with strong positive skew; n = 248) studies on crowdsourcing platforms (e.g., MTurk); 54% of the sample reported having completed between 0 and 5000 studies. Participants reported having completed such studies for an average of 3.73 years (SD = 2.86; n = 257), 3.33 months (SD = 2.79; n = 257), and 5.04 days (SD = 8.18; n = 245). Participants reported spending, on average, 3.94 hours (SD = 4.77) per day, over 6.24 days (SD = 9.60; n = 267) in a week, completing online studies. Finally, participants perceived themselves as *very experienced* (M = 5.05, SD = 1.09).

Materials and Measures

Demographic Information and MTurk Experience. We collected participants' basic demographic information: age, self-reported ethnicity, gender, and highest level of education (indexed to the American education system). Additionally, we collected information about participants' prior online study completion (e.g., "Approximately how many online studies have you completed on crowdsourcing platforms?", "Approximately how many days/hours per week/day you spend completing online studies?"), and experience

(e.g., “How would you rate your experience of completing online studies on the following scale?”, where *0 = Not very experienced, 3 = Some experience, and 6 = Very experienced*) of completing online studies.

Factors Affecting Decision to Participate (Adapted from Cook & Hoas, 2011; Appendix D). To understand factors that may influence participants’ decision to participate in psychological research, we asked them to read five statements (e.g., “I believe I’m contributing to science”) and rate to what extent they agreed or disagreed (*where 0 = Strongly disagree and 6 = Strongly agree*) with these statements. We also included an “other” option where participants could input a reason that influences their decision to participate; participants who entered a reason also rated to what extent they agreed or disagreed with the reason.

Pre-Existing Knowledge of Consent. To examine participants’ pre-existing knowledge of consent practices, we administered two types of questions. First, we presented participants with three broad, but related, open-text response questions (i.e., “According to the current ethics guidelines, [1] what information do you know must be provided about psychological research studies before participating? [2] what do you know your rights are as a participant? [3] what do you know you can do if you have concerns about psychological research studies?”). We administered these questions first to avoid providing participants with specific information through the questions (i.e., about aspects of consent including study purpose, discussion of risks etc).

Second, because we were specifically interested in participant’s pre-existing knowledge of specific consent domains—namely risks presented at consent—we developed 15 consent-related statements for the purpose of this study (e.g., “The consent form should provide me with sufficient information and adequate understanding of the research study to make a voluntary decision about participating”), and asked participants to rate the extent to

which they believed these statements were true or false (where *0 = Definitely false, 3 = Neither true nor false, and 6 = Definitely true*). We developed these statements based on consent guidelines from the British Psychological Society (BPS; 2021), Australian National Health and Medical Research Council (NHMRC; 2018), and American *Public Welfare Act* (2018). Of course, consent guidelines vary between the UK, Australia, and the US, as does the way that IRBs within and between these countries interpret these guidelines. Thus, we developed items that synthesised the key information across these guidelines. For example, we focused on critical areas of consent (e.g., relating to voluntariness, participant's rights, risks) that were prominent in all three guidelines, in addition to recommended areas of information for consent (e.g., incentives, sources of funding, community benefits etc.), that were only sometimes present in all three guidelines and/or guidelines had differences in their recommendations. Therefore, in line with our scale anchors, if participants were knowledgeable about general ethical guidelines, they should rate most of these statements between "neither true nor false" and "definitely true".

Our final 15 statements (current study: α = .86, Study 2b: α = .82) formed nine consent components (see Table 5.1 for specific statements within each consent component): voluntariness, purpose, methods, participant's rights, benefits, risks, incentives, and declarations of interest.

Participant Preferences for Consent. To examine participants' preferences for informed consent, we asked them to rate how strongly they agreed or disagreed (where *0 = Strongly disagree, 3 = Neither agree nor disagree, and 6 = Strongly agree)* with 17 statements (e.g., "I expect to be informed about the study's purpose"). Again, we developed these statements based on UK (BPS, 2021), Australian (NHMRC, 2018), and US (Public Welfare Act, 2018) consent guidelines. The final 17 statements (current study: α = .82, Study 2b: α = .78) mapped onto to the same nine consent components as the pre-existing

knowledge statements; see Table 5.1. We also asked participants to reflect on the statements they responded to here and describe anything they would like to change—either add in or take away—from these consent guidelines.

Criterion A Trauma Question (APA, 2013). For participants who consented to answering this single-item question[22], we asked them to think of their most traumatic or stressful event and whether if, during this event, they were exposed to death, actual or threatened injury, or actual or threatened sexual violence, in any of the following way(s): a) direct exposure, b) witnessing the trauma, c) learning that a relative or close friend was exposed to a trauma, d) indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g., first responders; i.e., Criterion A for PTSD in the DSM-5; APA, 2013).

[22] To ask participants this question, our IRB requested that we present participants with a second consent form specific to the Criterion A question. Doing so allowed us to capture participants' pre-existing knowledge and preferences for consent if they had experienced a past traumatic event; such participants may have otherwise avoided participating if a risk-warning was included in the first consent form.

Table 5.1

Descriptive Statistics for Pre-Existing Knowledge and Preferences Measures

Measure	Consent Component	*Mean*	*SD*	*n*
Guideline Specific Pre-Existing Knowledge				
1. “The consent form must provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate.”	Voluntariness	5.01	1.22	268
2. “The consent form must provide me with sufficient information and adequate understanding of the research study to make a voluntary decision about participating.”	Voluntariness	5.05	1.27	268
3. “The consent form must provide me with an adequate understanding of the study’s purpose.”	Purpose	3.66	2.05	268
4. “The consent form must provide me with an adequate understanding of the methods (e.g., “answering questionnaires”) that will be used in the study.”	Methods	4.24	1.57	268
5. “The consent form must include the expected duration of the study.”	Methods	4.34	1.72	268
6. “The consent form must provide me with information about declining to participate, including withdrawing from the research after participation has begun.”	Participant Rights	5.42	1.04	267
7. “The consent form must include contact details for researchers and Institutional Review Boards (i.e., ethics committees) should I have any complaints.”	Participant Rights	5.36	1.00	268
8. “The consent form must provide me with an adequate understanding of what potential personal benefits are involved in participating.”	Benefits	4.49	1.63	268
9. “The consent form must provide me with an adequate understanding of what potential community benefits are involved in participating.”	Benefits	2.77	1.93	268
10. “The consent form must provide me with an adequate understanding of what potential risks are involved in participating.”	Risks	5.31	1.07	268
11. “The consent form must warn me against participating if the study will be overly distressing (e.g., recalling a traumatic event).”	Risks	4.68	1.46	268

12. “The consent form must include information about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.41	0.95	268
13. “The consent form must include information about how the data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.96	1.32	268
14. “The consent form must explain what compensation I will receive.”	Incentives	4.91	1.53	268
15. “The consent form must include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.32	1.96	268
Guideline Specific Preferences				
1. “I expect that the consent form will provide me with enough information and understanding that I can make a voluntary decision about participating.”	Voluntariness	5.39	1.00	268
2. “I expect that the consent form will provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate.”	Voluntariness	5.21	1.05	268
3. “I expect to be informed about the study’s purpose.”	Purpose	3.89	1.94	268
4. “I expect to know what the study’s procedure is.”	Methods	4.31	1.59	268
5. “I expect to know what types of questions I will answer during participation (e.g., I expect to see sample questions prior to deciding to participate.”	Methods	2.76	2.08	268
6. “I expect to know the expected duration of the study.”	Methods	5.13	1.27	268
7. “I expect to be told what my rights are as a participant on the consent form (e.g., that I can withdraw from participating at any time).”	Participant Rights	5.46	0.94	268
8. “I expect to have contact information (e.g., email telephone number) for the researchers and relevant ethics board).”	Participant Rights	5.32	1.06	268
9. “I expect that I can contact the researchers and/or relevant ethics board if I have concerned about the research study.”	Participant Rights	5.37	0.99	268
10. “I expect that all possible benefits of participating are listed on the consent form.”	Benefits	3.89	1.81	268
11. “I expect that no benefits are listed on the consent form.”	Benefits	2.06	1.84	268

12. “I expect that all possible risks of participating are listed on the consent form, including risks that are unlikely to occur”	Risks	4.59	1.62	268
13. “I expect that no risks are listed on the consent form.”	Risks	1.47	1.83	268
14. “I expect to be told about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.29	1.08	268
15. “I expect to be told how that data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.85	1.48	268
16. “I expect to be told what compensation I will receive.”	Incentives	5.34	1.15	268
17. “I expect the consent form to include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.60	2.12	268

Procedure

To reduce the chance of bots/server farms completing our survey, participants first completed a Captcha screen, cultural check question, and had to obtain greater than 80% on an English Proficiency Test (see https://osf.io/gjryt for precautions outlined in full, alongside Moeck et al., 2022). Next, participants completed informed consent procedures, demographics, factors affecting decisions to participate, general pre-existing knowledge, guideline specific pre-existing knowledge, and guideline specific preferences questions.[23] In line with ethics requirements, we then presented participants with a new consent form that included details about the Criterion A trauma-exposure question. If participants consented, they viewed the Criterion A trauma-exposure question (Study 2a: $n = 232$; Study 2b: $n = 241$) and if they did not consent (Study 2a: did not consent: $n = 33$, did not respond to question: $n = 3$; Study 2b: did not consent: $n = 15$, did not respond to question: $n = 9$), they proceeded to debriefing procedures. Participants were compensated with $1.50 (USD) and debriefed in full.

Statistical Overview

We ran most of our analyses using SPSS 28, using null-hypothesis significance testing (NHST). Per our pre-registration, we also ran Bayes Factors using JASP (Version 0.15). For these analyses, we used Cauchy default priors (0.707) and followed Wetzels et al.'s (2011) guidelines for interpretation. Our strategy remained the same for Study 2b.

Thematic Analysis

Per our pre-registration, we initially used NVivo to identify broad themes present in our data. After review, we developed codes specific to each of our four open-ended pre-existing knowledge and desired change questions via an inductive approach (Braun & Clarke,

[23] After these questionnaires, participants went on to complete an imagined consent risk presentation options task and rate the risk presentation options. These data are reported in a separate manuscript currently under preparation.

2006). We applied the codes developed via NVivo 13 (2020, R1) to our data and refined the codes where required (e.g., where codes needed more specificity). We again recoded the data using the refined codes and measured inter-rater reliability between our two coders (NS; OM; interrater reliability range: 75% - 99%). Coders met to work through discrepancies. Our analysis strategy remained the same for Study 2b.

Results

Why do People Participate in Psychological Research Studies?

On average, participants strongly agreed that financial compensation (M = 5.04, SD = 1.15) influenced their decision to participate, followed by finding the studies interesting (M = 4.72, SD = 1.16), contributing to science (M = 4.51, SD = 1.24), and thinking the studies are a good use of their time (M = 4.41, SD = 1.30); participants indicated that they neither agreed nor disagreed (i.e., the midpoint) with feeling like the studies will help their own mental health (M = 3.04, SD = 1.95).[24] Pairwise comparisons[25]—see Supplementary Files at the end of this Chapter for results of all potential pairwise comparisons in full—confirmed that participants strongly agreed financial compensation influenced their decision to participate, more so than contributing to science (p < .001, d = 0.44, 95% CIs [0.23, 0.83]), helping their own mental health (p < .001, d = 1.25, [1.57, 2.43]), finding the studies interesting (p = .025, d = 0.28, [0.02, 0.62]), or feeling the studies are a good use of time (p < .001, d = 0.51, [0.01, 0.40]). In line with our pre-registration, we re-ran our analyses with *only* participants who consented to the Criterion A trauma-exposure question (n = 232). The comparison between financial compensation and finding the studies interesting was no longer statistically significant, p = .063, d = 0.26, 95% CIs [-0.01, 0.59]; all other results were unchanged.

[24] Three participants chose not to respond to one of the reason items (different items per participant) and therefore were left out of the analysis. Participants included in these analyses: n = 265.

[25] Because we changed the way we collected data for decision to participate prior to starting data collection—that is, we asked people to rate their agreement on a Likert-type scale—we deviated from our pre-registered plan to use Chi-square comparisons. This was due to an oversight on the author's behalf and also applies to this analysis in Study 2.

Participants also stated other reasons that influence their decision to participate, including: that studies helped them learn something new about either themselves/something else (e.g., psychology; 27.1%; *M* = 5.54, *SD* = 0.66) or to pass the time/cure boredom (16.7%; *M* = 5.25, *SD* = 0.89), that they liked helping researchers and/or others (14.6%; *M* = 5.00, *SD* = 1.00), for fun/entertainment (14.6%; *M* = 4.86, *SD* = 1.46), or for a reason covered by our existing items (e.g., financial gain, interesting, contribution to science; 12.5%; *M* = 5.83, *SD* = 0.41), skill-building (e.g., typing, cognitive abilities; 6.3%; *M* = 6.00, *SD* = 0.00), mental challenge (4.2%; *M* = 5.50, *SD* = 0.71), to share opinion (2.1%; *M* = 6.00, *SD* = 0.00), and for study advancement (i.e., helps people get invited to larger surveys; 2.1%; *M* = 6.00, *SD* = 0.00).

Overall, our findings document novel reasons that MTurk workers choose to participate in psychological research studies. Here, participants strongly endorsed financial compensation and finding the studies interesting as reasons for participation. These reasons somewhat differ from prior trauma-related research investigating women's experiences with intimate partner violence, that found participant's *main* reasons for participation were "I was curious" and "To help others" (Hebenstreit & DePrince, 2012). Of course, one of the key features of MTurk is that workers can complete tasks for "money" and are considered part of a "24x7 workforce" (Amazon Mechanical Turk, 2018). Thus, it is perhaps no surprise that MTurk workers endorsed this reason the most and that, as such, they differ from specific trauma samples.

Our results also contribute to existing research examining MTurk worker characteristics. Our findings lend support to the idea that MTurk workers likely approach Human Intelligence Tasks (HITs) based on compensation—as Chilton and colleagues (2010) also indicated—rather than content. In the context of trauma-related research (i.e., here, responding to a Criterion A question), our results also point toward the idea that MTurk

workers engage with trauma-related research because they find it interesting, in addition to for compensation purposes.

What do Participants Already Know About Consent Practices?

We first turn to the results of our thematic analysis of participants' responses to the four open-ended questions (see Table 5.2 for code themes, examples, and frequencies).

Q1: According to Current Ethics Guidelines, What Information do you Know you Must be Provided About Psychological Studies Before Participating? Overall, some participants reported knowing that, prior to consenting to participate, they should receive information related to: risks (39.6%), researchers and IRBs (including contact information; 31%), confidentiality (29.9%), study's purpose (23.5%), method (20.9%), rights (19%), and compensation (17.9%). To a lesser extent, participants reported knowing they should also receive information regarding: research outputs (i.e., what will be "done" with the research; 14.9%), informed consent (10.8%), benefits (10.1%), and data storage (9.7%). Few participants reported that they should receive information related to study demands (e.g., exclusion criteria; 2.6%), contact information for mental health services (2.2%), and funding of the research (0.7%). A further 7.1% of participants responded that they were unsure what information they should receive; 11.2% of responses were unclear and were therefore not coded into a relevant theme.

Table 5.2

Thematic Coding Tables with Examples and Frequencies for Crowdsourced Participants

Q1: According to current ethics guidelines, what information do you know you must be provided about psychological studies before participating?	
Code	Frequency (%)
Unclear response: Responses that do not make sense or answer the question	11.2
Study purpose: Responses that refer to including the study's purpose (e.g., "The purpose for which the study is being done…", "…why the study is being done…")	23.5
Participant's rights: Responses that refer to participant's rights. For instance, right to withdraw from the study, right to withdraw data (e.g., "…A statement saying that I have the right to end the study early if I start to feel uncomfortable with the questions", "That it is completely voluntary and I can leave the study if I want to".	19.0
Methods: Responses that refer to methodological information, such as what participants will have to do or approximate time commitments (e.g., "…how long they will take in estimate…", "What is involved…", "…what the study consisted of".	20.9
Informed consent: Responses that refer researchers having to gain and/or provide consent forms (e.g., "Informed consent…", "Consent…", "consent to undertaking the study")	10.8
Description of benefits: Responses that refer to explaining possible benefits to participation (e.g., "Benefits…", "…the benefits of the study")	10.1
Description of risks: Responses that refer to explaining possible risks to participation (e.g., "If the study is going to involve risk such as photos that may trigger a response", "…you have to be given information about potential risks…")	39.6
Confidentiality: Responses that refer to how data will be handled, such as whether the data will be deidentifiable, anonymous etc. (e.g., "…privacy practices…", "…what will be done with your information", "limits to confidentiality…")	29.9
Contact information: Responses that refer to including information about the researchers and/or IRBs, including their contact information	31.0
Study demands: Responses that refer to inclusion or exclusion criteria for the study, outside of method-related information (e.g., "…age allowed to participate…", "…what qualifications you need to have"	2.6
Mental health service information: Responses that refer to including directions to mental health services, mental health support, helplines etc. (e.g., "…provide ways to contact help if you are upset by something during the study…")	2.2

Funding of research: Responses that refer to overall research funding, individual funding of researchers, and/or researcher affiliations (e.g., "…the sponsor of the study…")	0.7
Compensation: Responses that refer to informing participants about compensation (e.g., "…what compensation I will be offered…")	17.9
Unsure of information: Responses that indicate the participant does not know what information they should be provided with (e.g., "unsure", "Well, being absolutely honest I have no idea")	7.1
Research outputs: Responses that refer to how the data will be used (e.g., "…what will be done with the results…")	14.9
Data storage: Responses that refer to data storage and/or issues related to data storage (e.g., "…how my information will be stored…")	9.7
Q2: According to current ethics guidelines, what do you know your rights are as a participant?	
Unclear response: Responses that do not make sense or answer the question	1.9
Agreement: Responses that indicated participants knew what their rights were (e.g., "Mostly, yes")	26.1
Withdraw from participation: Responses that refer to withdrawing from participation at any point and/or choosing not to answer certain questions (e.g., "I can quit at any time", "I am allowed to withdraw from the study at any point")	50.0
Withdraw data from study: Responses that refer to withdrawing data from a study (e.g., "I am able to request that my data be remove or not used")	10.8
Informed consent: Responses that refer to the overall informed consent process, for instance receiving a consent form or reading a consent form for more information on rights (e.g., "They should ask for my consent to participate in the study", "…people need to be provided consent in order to participate")	10.8
Voluntariness: Responses that refer to not feeling coerced or participation being a voluntary choice (e.g., "…to participate is voluntary", "I know that it is voluntary")	2.6
Confidentiality: Responses that refer to having the right to know how data will be handled (e.g., "Personal information will not be shared", "I have the right to anonymity")	16.0
Contact information: Responses that refer to having the right to contact researchers and/or IRBs (e.g., "I have the right to contact the researcher with any concerns")	10.8
Methods: Responses that refer to having the right to know what they will need to do in a study (e.g., "To be told what you will be asked to do in the study", "…what you will be asked to do if you are in the study"	3.4
Violation of rights: Responses that refer to information that is in opposition to participant's rights (e.g., "There are no rights", "…if I do complete a study then any information I give can be used by the researchers in whichever way they desire")	2.6

Inconsistent with rights: Responses that refer to an aspect of participant's rights that varies from study-to-study (e.g., "I will be kept anonymous", "…anonymity will be maintained")	4.9
Unsure of rights: Responses that refer to not knowing what rights they have (e.g., "No", "I don't really know", "not really")	14.6
Risk information: Responses that refer to having the right to appropriate risk information (e.g., "To be informed of any risks", "To be told the reasonably foreseeable risks of being in the study")	2.2
Q3: According to current ethics guidelines, what do you know you can do if you have concerns about psychological research studies?	
Unclear response: Responses that do not make sense or answer the question	3.0
Agreement: responses that indicate they know who to contact (e.g., "Yes I do know")	17.2
Contact information provided: Responses that refer to using the contact information, usually for researchers and/or IRBs, provided	72.4
Contacting employer: Responses that refer to contacting the organisation/crowdsourcing platform (e.g., "I believe my only recourse is to write to…Amazon Mechanical Turk", "Through other entities, such as a corporation"	4.1
Unsure: Responses that refer to not knowing what to do (e.g., "No", "No idea")	6.0
Action other than those already mentioned (e.g., using contact information provided): Responses that refer to other actions relevant to consent (e.g., "Withdraw your consent to use your data", "…withdraw", "most requesters leave help phone number or 1-800 numbers")	13.8
Q4: What do participants want to change, if anything, about current consent guidelines?	
Unclear response: Responses that do not make sense or answer the question	2.2
No change: Responses that indicate participants do not want to change current guidelines (e.g., "nothing I would add", "no, I do not wish to change anything", "They seem to be very well covered and I don't have any issues with them")	61.9
More detail on aspects of consent that already exist: Responses that refer to providing more information about some aspect of consent (e.g., "It would be better to have clearer language around the purpose of the study…more details should be given", "Sample questions and if there will be writing involved", "…should always clearly state if there's potential for harm in the study")	17.2
Improved risk information: Responses that refer to including and/or making risk information more obvious (e.g., "I would want greater transparency on things like risks", "I've been shown videos/photos of gruesome scenes – mangled corpse, tortured animals with absolutely no warning", "…disturbing images must be preceded by warnings – if this is already the case then I def have taken studies that do not follow the guidelines")	4.1

Presentation of consent information: Responses that refer to improving consent form presentation (e.g., “I think most people skim over these consent forms, so I think it would help if the important parts were in bold face type and the pertinent information be more noticeable in some way”, “I would only like for the information to be given in a manner as succinct and un-legalistic as possible”)	3.0
Change that is already enacted by guidelines: Responses that refer to changing an aspect of consent that should already be enacted (e.g., “A true timeline of how long it might take and a number for the ethics board”, “Many European researchers have no IRB listed”, “I would definitely like to see the amount of time expected”)	11.2
Fair pay: Responses that refer to better pay or better pay conditions (e.g., “…adding the hourly wage equivalent would be helpful”, “…it should not be ok to exploit workers with low pay…”, “pay minimum wage”)	6.3
Removing parts of consent that current exist: Responses that refer to removing parts of consent that are currently used (e.g., “I don’t see the need to provide potential benefits other than the compensation amount”, “I would drop all of the ethics guidelines…”, “I think you should remove IRB information since those are usually fake anyway”)	1.9
Did not respond to question: Responses that were left blank	3.4
Unsure: Response indicates person is unsure whether anything should change (e.g., “I am not sure”)	0.7
More accurate information: Responses that refer to improving the accuracy of information provided at consent (e.g., There’s many surveys I’ve come across that have a listed time it’ll take to complete, but it is far from the actual time the survey actually takes to complete”)	6.7
Design-specific changes: Responses that refer to altering design-related information (e.g., “…ethics guidelines should ban the practice of burying attention checks on the page with the guidelines”, “I feel that the use of attention check questions can negatively affect ‘good faith’ study takers…”)	1.5
Deceit and debriefing: Responses that refer to including debriefing information and/or strategies to address when deceit is used (e.g., “I would like there to be a debriefing statement after the study is done…”, “I would like the guidelines to include a section before taking the study that states whether or not information told to participants in the study could potentially be false.”)	2.2
Data management: Responses that refer to specific data management procedures (e.g., “What happens if data is hacked”)	1.5
Referral to mental health services: Responses that refer to including referral to mental health services (e.g., “…if a person is triggered by a study there should be resources linked for mental health”)	0.4
Enforcement of ethical guidelines: Responses that refer to enforcing guidelines, ensuring people comply with current guidelines or consistency between guideline enactment (e.g., “Change them from guidelines to rules and provide some enforcement…”, “I would like all information to be mandatory, as opposed to some of it being mandatory”, I believe I have seen various guidelines amongst surveys. It would be quite helpful, if all the prerequisites are the same…”).	3.0

Q2: …What do you Know your Rights are as a Participant? Approximately half of our participants indicated that they had the right to withdraw from participation in a study (50%); 26.1% of participants agreed with the idea that they knew what their rights were as a participant, while 14.6% of participants reported being unsure of their rights. Some participants reported knowing they could withdraw their data from a study (10.8%), had the right to informed consent (e.g., via viewing a consent form; 10.8%), contact information (for researchers and/or IRBs; 10.8%), and confidentiality (16%). Few participants reported to knowing that they had the right to not feel coerced etc. during the consent process (i.e., voluntariness; 2.6%), that they should receive method-related information (3.4%), and relevant risk information (2.2%). Interestingly, a few participants reported information that was inconsistent with their rights (e.g., remaining anonymous in all studies when such information may vary study-to-study; 4.9%) and in violation of their rights (e.g., believing they have no rights; 2.6%). Finally, 1.9% of responses were unclear and therefore not coded.

Q3: …What do you Know you can do if you Have Concerns About Psychological Research Studies? Many participants reported knowing they could use the contact information provided for researchers and/or IRBs if they had any concerns about psychological research studies (72.4%); some participants also reported agreeing with the idea that they knew what to do (17.2%). Other participants reported contacting the employer (i.e., MTurk; 4.1%) or actions other than contacting those already mentioned (e.g., not participating; 13.8%). A few people reported they were unsure (6%) and some provided unclear responses to the question (3%).

Together, these results have three overarching implications. First, participants have *some* basic understanding of what information they should receive prior to participating in psychological research. However, given less than half of participants recalled critical consent components (e.g., methods, risks), baseline knowledge about consent appears low in

crowdsourced participants. Perhaps some pre-existing knowledge, combined with the *choice* to focus on self-relevant consent information (e.g., method and risk information; Douglas et al., 2021), is sufficient for participants to believe they have engaged with informed consent. Second, participants have a moderate understanding of their participation rights (i.e., knowing they can withdraw if required). Concerningly though, participants' knowledge about other participant rights (e.g., confidentiality) is minimal, and several participants expressed they do not know what their rights are. Given our sample perceives themselves—on average—as highly experienced in completing psychological research studies, it is problematic from an ethical standpoint that participants' knowledge of their participation rights is not more comprehensive. Third, most participants know they can reach out to relevant researchers and/or IRBs if they have concerns about a study, which is promising. Additionally, some participants reported other avenues of action, including withdrawing from the research study, if they had concerns. However, it is unclear how often participants express concern directly to researchers and/or toward IRBs. While we imagine these rates are low given research continues—and is usually monitored by IRBs—establishing whether participants reach out and how satisfied they are with this process is an important future direction. Particularly when here, we found some anecdotal reports of participants being unable to reach researchers and/or IRBs or believing that contact information is usually fake since they do not hear back from people. Though, we note, some of these participant reports could be conflated with market research given responses were sometimes vague (e.g., referred to IRB but not as being linked to a university).

Pre-existing Knowledge Statements. Next, we consider participants' responses to our 15 consent-related statements rated on a true/false agreement scale. Descriptive statistics, along with consent statements listed in full, appear in Table 5.1. Overall, participants showed good understanding of critical consent guidelines: they rated six ethics statements centring

around voluntariness, participant rights, risks, and confidentiality as "definitely true" (i.e., > 5, where *6 = Definitely true*), and six statements focusing on methods, risks, confidentiality, and incentives as somewhat true (i.e., > 4).

Participants demonstrated less knowledge in terms of one area of consent: they rated knowing the study's purpose as "neither true nor false" (i.e., > 3). They also rated two statements— relating to benefits (i.e., community benefits) and declarations of interest consent components—as "somewhat false" (> 2, where *0 = Definitely false*).[26] However, only the *Australian* research guidelines include these specific consent components (the UK and US guidelines do not), and even then, the Australian guidelines suggest that this information should be outlined to participants, but it generally "…should be kept distinct from…" critical consent information that may impact a participant's voluntary decision to participate (e.g., sufficient information about purpose, methods, participant rights, risks etc.; NHMRC, 2018, p. 16-17). Therefore, these aspects of consent information may be lesser known to participants or less salient in consent forms.

Our results for pre-existing knowledge *statements* contrast our findings for pre-existing knowledge open-text questions. Specifically, our statement data indicates that crowdsourced participants have a better understanding of critical consent components (e.g., voluntariness, participant rights etc.) than the open-text response data did. Taking data from both measurement types together, we consider crowdsourced participant's pre-existing knowledge of consent practices low-to-moderate.

What are Participants' Consent Preferences (i.e., What do They Expect From IRBs and Researchers)?

[26] We repeated these analyses after removing participants who did not consent to answering the Criterion-A question. There was minimal difference between means (i.e., 0.01-0.30 change) and therefore we include results for the interested reader at: https://osf.io/gnwq4/.

Next, we examined participants' *preferences* for consent practices (see Table 5.1 for descriptive statistics and statements in full). Participants reported strong preferences (i.e., > 5, where *6* = *Strongly agree*) in favour of eight consent statements, including consent components such as: voluntariness, methods, participant's rights, confidentiality, and incentives; and somewhat strong preferences (i.e., > 4, "somewhat agreed") for three ethics statements, across the methods, risks, and confidentiality components. Participants indicated that they neither agreed nor disagreed—that is, a neutral preference (> 3)—with two consent statements across the purpose and benefits components.

Moreover, participants indicated somewhat strong (i.e., > 2, where *0* = *Strongly disagree*) disagreement with three consent statements, across the methods, benefits, and declarations of interest components; and strong disagreement with one statement related to risks; specifically, participants indicated that having risks listed on the consent form is important to them.[27] Thus, in terms of risk, our results suggest that participants fall somewhere between wanting all possible risks listed and having no risks listed on the consent form. Our finding likely reflects individual variability for preferences regarding risk information; for example, we know within a health context that some people *avoid* health-related information (e.g., if a person considers themselves healthy, they may avoid information that causes them to question their healthy status and thereby minimise potential anxiety; Brashers, 2001; Brashers et al., 2002). Thus, some people may prefer having less risk information while others prefer having all possible information to inform their decision.

Regarding crowdsourced participants then, our results suggest that informed consent practices should continue to include critical information, including information related to expected duration of study, reasonably foreseeable risks, confidentiality, participant rights

[27] We repeated these analyses after removing participants who did not consent to answering the Criterion-A question. There was minimal difference between means (i.e., 0.01-0.30 change) and therefore we include results for the interested reader at: https://osf.io/gnwq4/.

(i.e., withdrawal from participation), and incentives (i.e., whether compensation is available). Importantly, these preferences should come together to endorse voluntariness (i.e., providing participants with enough information and understanding to make an informed decision), a critical consent component that participants showed a strong preference for. Such preferences for consent are mostly consistent with the areas of consent forms that participants tend to read first (e.g., method and confidentiality; Douglas et al., 2021); noting however that prior research was conducted with undergraduates. Surprisingly, crowdsourced participants showed a neutral preference for study purpose and benefit information, yet still indicated they wanted some benefits included at consent. One strategy to provide participants with more information at consent—making them more informed—has been to include example questions in the method section. But here, crowdsourced participants showed a somewhat strong preference *against* such information being included as part of the consent process. Therefore, such method information (i.e., question examples) is one area we could consider excluding at consent in favour of consent readability and form length (e.g., Albala et al., 2010).

Do Participant Consent Preferences Differ Based on Prior Trauma-Exposure?[28]

Next, we examined whether participant's consent preferences differed based on prior trauma-exposure. Here, we could reliably detect effects at $d = 0.38$. Comparable to prior Criterion A traumatic event exposure estimates (e.g., Benjet et al., 2015; Bridgland & Takarangi, 2022; Kilpatrick et al., 2013), approximately a third of crowdsourced participants reported trauma-exposure (61.64%; no trauma-exposure = 38.36%).

We ran a series of independent samples t-test and corrected for multiple comparisons (i.e., adjusted statistical significance: $p < .003$). Across the 17 consent preference statements,

[28] We also tested whether prior trauma-exposure influenced participant's pre-existing knowledge; it was not. However, because this analysis was not central to our question of participant preferences, nor was it pre-registered, we include here https://osf.io/gnwq4/ for the interested reader.

our analyses revealed that preferences did not differ between trauma-exposed and non-trauma-exposed participants, *p*s: .010 - .925, *d*s: 0.13 - 0.38 (see Table 5.3 for results in full). We found substantial (i.e., $BF_{10} = 6.22$) and anecdotal (i.e., $BF_{10} = 1.31$) evidence in favour of the alternative hypothesis (i.e., that there is a group difference)—relative to the null hypothesis—for two preference statements across two consent components: methods (i.e., study duration) and voluntariness, respectively. For study duration, on average, trauma-exposed participants more strongly agreed (i.e., "agree" to "strongly agree") with wanting to know the expected duration of the study than non-trauma-exposed participants, who less strongly agreed (i.e., "somewhat agree" to "agree"); a small-to-medium effect size. In terms of voluntariness, on average, trauma-exposed participants had a slightly stronger preference for this voluntariness statement than non-trauma-exposed participants. But both groups still had a strong preference toward the voluntariness statement (i.e., "agree" to "strongly agree") and the effect size was small. Thus, although our Bayes Factors showed evidence in favour of the alternative hypothesis (i.e., that there is a difference between trauma-exposed groups), both groups reported agreement in a similar direction. For the remaining preference statements, we found substantial evidence (i.e., BF_{10}s: 0.15 – 0.27), and anecdotal evidence (i.e., BF_{10}s: 0.34 – 0.82), in favour of the null hypothesis, relative to the alternative.

Table 5.3

Descriptive and Inferential Statistics, Including Bayes Factors, for Pre-Existing Knowledge and Consent Preference Statement Group Comparisons

		Trauma-Exposed (*n* = 143)	Non-Trauma-Exposed (*n* = 89)			
Measure	Consent Component	*M(SD)*	*M(SD)*	*p*	*Cohen's d*	BF_{10}
Guideline Specific Pre-Existing Knowledge						
1. "The consent form must provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate."	Voluntariness	5.08 (1.18)	4.91 (1.24)	.304	0.14	0.24
2. "The consent form must provide me with sufficient information and adequate understanding of the research study to make a voluntary decision about participating."	Voluntariness	5.06 (1.27)	5.01 (1.27)	.794	0.04	0.15
3. "The consent form must provide me with an adequate understanding of the study's purpose."	Purpose	3.47 (2.09)	3.84 (1.95)	.174	0.18	0.35
4. "The consent form must provide me with an adequate understanding of the methods (e.g., "answering questionnaires") that will be used in the study."	Methods	4.36 (1.58)	4.07 (1.62)	.180	0.18	0.35
5. "The consent form must include the expected duration of the study."	Methods	4.46 (1.62)	4.22 (1.76)	.296	0.14	0.25
6. "The consent form must provide me with information about declining to participate, including withdrawing from the research after participation has begun."	Participants Rights	5.48 (0.95)	5.27 (1.27)	.155	0.19	0.38
7. "The consent form must include contact details for researchers and Institutional Review Boards (i.e., ethics committees) should I have any complaints."	Participants Rights	5.39 (1.04)	5.26 (1.03)	.342	0.13	0.23
8. "The consent form must provide me with an adequate understanding of what potential personal benefits are involved in participating."	Benefits	4.52 (1.61)	4.43 (1.62)	.678	0.06	0.16
9. "The consent form must provide me with an adequate understanding of what potential community benefits are involved in participating."	Benefits	2.57 (1.92)	2.91 (1.84)	.189	0.18	0.33

10. “The consent form must provide me with an adequate understanding of what potential risks are involved in participating.”	Risks	5.40 (0.99)	5.22 (1.09)	.210	0.17	0.31
11. “The consent form must warn me against participating if the study will be overly distressing (e.g., recalling a traumatic event).”	Risks	4.79 (1.46)	4.46 (1.45)	.095	0.23	0.55
12. “The consent form must include information about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.43 (0.94)	5.36 (0.98)	.603	0.07	0.17
13. “The consent form must include information about how the data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	5.00 (1.33)	4.89 (1.23)	.521	0.09	0.18
14. “The consent form must explain what compensation I will receive.”	Incentives	5.02 (1.46)	4.83 (1.52)	.344	0.13	0.23
15. “The consent form must include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.11 (1.84)	2.65 (2.00)	.037	0.28	1.16
Guideline Specific Preferences						
1. “I expect that the consent form will provide me with enough information and understanding that I can make a voluntary decision about participating.”	Voluntariness	5.52 (0.86)	5.24 (1.11)	.032	0.29	1.31
2. “I expect that the consent form will provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate.”	Voluntariness	5.34 (0.90)	5.09 (1.14)	.061	0.25	0.76
3. “I expect to be informed about the study’s purpose.”	Purpose	3.64 (2.05)	4.15 (1.76)	.048	0.26	0.82
4. “I expect to know what the study’s procedure is.”	Methods	4.37 (1.63)	4.17 (1.48)	.342	0.13	0.23
5. “I expect to know what types of questions I will answer during participation (e.g., I expect to see sample questions prior to deciding to participate.”	Methods	2.55 (2.11)	3.00 (2.05)	.114	0.21	0.48
6. “I expect to know the expected duration of the study.”	Methods	5.34 (1.00)	4.89 (1.41)	.010	0.38	6.22
7. “I expect to be told what my rights are as a participant on the consent form (e.g., that I can withdraw from participating at any time).”	Participants Rights	5.49 (0.97)	5.36 (0.91)	.310	0.14	0.24
8. “I expect to have contact information (e.g., email telephone number) for the researchers and relevant ethics board).”	Participants Rights	5.36 (1.00)	5.17 (1.18)	.180	0.18	0.34

9. “I expect that I can contact the researchers and/or relevant ethics board if I have concerned about the research study.”	Participants Rights	5.43 (1.00)	5.24 (1.01)	.162	0.19	0.37
10. “I expect that all possible benefits of participating are listed on the consent form.”	Benefits	3.85 (1.82)	3.99 (1.78)	.558	0.08	0.17
11. “I expect that no benefits are listed on the consent form.”	Benefits	2.00 (1.83)	2.02 (1.69)	.925	0.01	0.15
12. “I expect that all possible risks of participating are listed on the consent form, including risks that are unlikely to occur”	Risks	4.62 (1.65)	4.51 (1.55)	.615	0.07	0.17
13. “I expect that no risks are listed on the consent form.”	Risks	1.28 (1.77)	1.55 (1.75)	.257	0.15	0.27
14. “I expect to be told about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.33 (1.04)	5.11 (1.22)	.151	0.20	0.39
15. “I expect to be told how that data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.83 (1.57)	4.81 (1.35)	.908	0.02	0.15
16. “I expect to be told what compensation I will receive.”	Incentives	5.45 (1.03)	5.24 (1.19)	.152	0.19	0.39
17. “I expect the consent form to include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.35 (2.11)	2.89 (2.06)	.058	0.26	0.15

With no multiple comparison correction, three of the preference statements reach traditional significance (i.e., < .05; see Table 5.3). Two of these statements—expected duration (p = .010) and voluntariness (p = .032)—are the statements reflected in our Bayes Factor results above. A third statement related to study purpose also reached significance (p = .048). We however interpret this result with caution given the p value is close to the cut off, the effect size is small, and both groups are positioned somewhere between "neither agree nor disagree" and "somewhat agree".

Altogether, our results suggest that generally, crowdsourced participants' consent preferences are similar *irrespective* of prior trauma-exposure. Importantly, participants' preferences regarding the communication of risks associated with participation did not seem to differ based on trauma-exposure. Our results suggest trauma-exposed participant (versus non-trauma-exposed) prefer statements related to voluntariness. This finding underscores the importance of providing trauma-exposed people with adequate information to make an *informed decision*, showing respect for them as people and supporting their sense of autonomy (e.g., NHMRC, 2018; Newman & Kaloupek, 2009); two such factors that are often absent during traumatic event exposure. Our finding that trauma-exposed participants have a stronger preference for consent information related to expected study duration likely feeds into the idea of supporting informed decision-making. Hence, these are two areas that may be important to focus on during consent for crowdsourced participants, particularly when approximately three-quarters of our sample reported prior trauma-exposure, i.e., representing the "invisible" trauma-exposed participants of psychology research (Becker-Blease & Freyd, 2006; Newman et al., 2006).

What do Participants Want to Change, If Anything, About Current Consent Guidelines? More than half our participants were currently satisfied with ethical guidelines, i.e., wanted no change (61.9%). Apart from wanting more detail about aspects that should

already be part of consent forms (17.2%), some notable change ideas—suggested by a minority of participants—related to more accurate information (e.g., about timeframe of completion; 6.7%), fairer pay (6.3%), and improved risk information (e.g., more obvious risk-warnings; 4.1%). Alarmingly, regarding risk information, several participants indicated they had been shown potentially disturbing content (e.g., photos/videos) without being informed of the risks. A few participants requested changes around: presenting consent information (3.0%); enforcing ethical guidelines (3.0%), including information related to deceit (and debriefing procedures; 2.2%), specific data management procedures (1.5%) and making design-specific changes (e.g., not using attention checks during consent; 1.5%); removing parts of the consent form that already exist (1.9%); and including referrals to mental health services (0.4%). Of note, 11.2% of participants requested changes that should already be enacted via current guidelines (e.g., information regarding risks, researcher/IRB contact information, time commitment, information presented in an easy-to-read way) though may not be reflected in consent forms people actually view; 3.4% of participants did not respond to the question, 2.2% of participants provided unclear answers, and 0.7% expressed they were unsure whether the guidelines should change.

Together, our crowdsourced sample provided change suggestions based on issues specific to MTurk. For instance, several participants cited concerns over not being paid enough or even that they should be paid *more* if the research involves certain tasks (e.g., viewing traumatic content). Yet, for researchers, these concerns present an interesting dilemma since compensation should be proportionate to research requirements (e.g., to compensate travel) and should not be coercive (see NHMRC, 2018, p. 17 and Public Welfare Act, 2018). Thus, particularly where trauma-related research is concerned on MTurk, increasing pay *because* participation involves trauma-related content would be coercive; that is, it could encourage participants to take additional risks.

Participants also suggested several improvements that are generally easy for researchers and/or IRBs to implement. These suggestions included providing detailed information regarding data use, researcher/IRB contact details, stating deception may be used, and highlighting risk information (e.g., bolded, underlined). Moreover, some participants reported information consistent with IRBs and/or researchers not engaging in ethical practices during informed consent procedures (e.g., not including IRB information). Relatedly, several participants indicated "changes" that, according to ethical guidelines, should already be enacted by researchers and/or IRBs. Therefore, these findings serve as a reminder to IRBs and researchers to positively engage with the ethical process. Finally, many participants were concerned about the accuracy of advertised participation time estimates. One solution, which some researchers likely already employ, is to pilot surveys for time (e.g., pilot within lab using people naïve to the design, conduct a small online pilot to confirm time). Within some survey programmes (e.g., Qualtrics), researchers can also check the median completion time and adjust time estimates accordingly.

Study 2b

Method

Participants

As in Study 2a, we aimed to collect $N = 260$ (Schönbrodt & Perugini, 2013; 2018). We collected 272 undergraduate participants using the Flinders University SONA system. However, we excluded seven participants for failing all three attention checks (e.g., Moeck et al., 2022), resulting in our final sample of $N = 265$.

Our sample were mostly women (82.3%; men = 16.2%; other = 0.8%; prefer not to say = 0.8%) aged 17 – 54 ($M = 20.52$, $SD = 5.84$) of Caucasian (or white) ethnicity (50.8%; mixed = 6.4% [e.g., Fiji-Italian], Asian = 2.7%, English = 2.3%, Indian = 1.9%, Japanese =

1.1%, other = 7.9% [e.g., Aboriginal Australian, Italian, Hispanic]; participants also reported their nationality: 25.8% [e.g., Australian]). Our sample's highest level of education, on average, was high school/equivalent (78.9%; associate degree/diploma or certificate = 12.5%, bachelor's degree = 8.3%, primary school = 0.4%). Overall, participants reported completing an average of 5.43 psychological studies (SD = 5.82; n = 258)[29]; the length of time (i.e., how long) participants had been completing these psychological studies was most commonly for one year (15.3%), although responses varied as high as three years (3.1%) to as low as < 24 hours (4.6%; see Supplementary Files at the end of this Chapter for statistics in full). On average, participants perceived their experience in completing psychological studies as somewhat experienced (M = 2.65, SD = 1.51; where *0 = Not very experienced, 3 = Somewhat experienced, and 6 = Very experienced*).

Procedure

Most procedural aspects were identical to Study 2a. However, we removed questions specific to crowdsourcing platforms (e.g., "Approximately how many online studies have you completed on crowdsourcing platforms?", Approximately how many days/hours per week/day you spend completing online studies?"). Participants were also awarded credit for their participation (0.5 credits).

Results

Why do People Participate in Psychological-Research Studies?

On average, undergraduates somewhat agreed they participated in psychological studies because they found them interesting (M = 4.36, SD = 1.12; on a 7-point scale, where *6 = Strongly agree*), followed by contributing to science (M = 4.13, SD = 1.14). Participants indicated they neither agreed nor disagreed with participating because they felt the studies

[29] We removed unclear responses from this descriptive analysis (e.g., 2 topics, a lot, I am in my first year) because we could not accurately code them, however due to the nature of our sample, we can assume many participants were participating in psychological research for the first time that year.

were a good use of their time (M = 3.52, SD = 1.36) or that participating helped their own mental health (M = 2.97, SD = 1.45); and participants somewhat disagreed that they participated because the studies benefited them financially (M = 2.11, SD = 1.75), likely because they received course credit. We confirmed—using pairwise comparisons—that participants somewhat agreed that finding studies interesting influenced their decision to participate, more so than contributing to science (p = .046, d = 0.20, 95% CIs [0.002, 0.49]), feeling the studies are a good use of their time (p < .001, d = 0.67, [0.61, 1.00]), help with their mental health (p < .001, d = 1.07, [1.16, 1.67]) or benefit them financially (p < .001, d = 1.53, [1.94, 2.62]; see Supplementary Files for comparisons in full). We also repeated these analyses without participants who did not consent to answering the Criterion A question (n = 237) and one result changed: the comparison between finding studies interesting and contributing to science was no longer statistically significant, p = .103, d = 0.20, 95% CIs [-0.02, 0.46].

Thirty-eight participants gave other reasons that influence their decision to participate, including: completing studies for credit or as part of course requirements (76.9%; M = 5.83, SD = 0.38), gaining experience or helping them learn more about psychology/psychological research (15.4%; M = 5.40, SD = 0.55), and contributing to psychological science (7.7%; M = 5.33, SD = 0.58).

Here, our results indicate that undergraduates choose to participate in psychological research studies out of interest and because they feel like they are contributing to science (including psychological science). Such reasons fit with the pedagogical experience undergraduate participation seeks to provide (e.g., Boyer Commission, 1998; Kligo et al., 2014), and empirical links between undergraduate research participation and university satisfaction (Bowman & Holmes, 2018).

Interestingly, we found participants somewhat disagreed with receiving financial compensation as a reason to participate in psychological research. While we did not offer financial compensation in the current study, we know that many on-campus studies do. Further, ~14% of our sample specified the reason for their participation was based on course credit allocation. Thus, although IRBs may be concerned about course credit increasing coercion, our data suggest otherwise. Here however, undergraduates had the option to complete an assignment if unwilling to participate in research, therefore implementing this approach in other undergraduate samples could foster scientific interest in undergraduates (versus coercion).

What do Participants Already Know About Consent Practices?

We now turn to the results of our thematic analysis of participants' responses to our open-ended questions (see Table 5.4 for code themes, examples, and frequencies).

Table 5.4

Thematic Coding Tables with Examples and Frequencies for Undergraduate Participants

Q1: According to current ethics guidelines, what information do you know you must be provided about psychological studies before participating?	
Code	Frequency (%)
Unclear response: Responses that do not make sense or answer the question	8.7
Study purpose: Responses that refer to including the study's purpose (e.g., "The purpose for which the study is being done…", "…why the study is being done…")	41.9
Participant's rights: Responses that refer to participant's rights. For instance, right to withdraw from the study, right to withdraw data (e.g., "…A statement saying that I have the right to end the study early if I start to feel uncomfortable with the questions", "That it is completely voluntary and I can leave the study if I want to".	34.7
Methods: Responses that refer to methodological information, such as what participants will have to do or approximate time commitments (e.g., "…how long they will take in estimate…", "What is involved…", "…what the study consisted of".	54.3
Informed consent: Responses that refer researchers having to gain and/or provide consent forms (e.g., "Informed consent…", "Consent…", "consent to undertaking the study")	31.3
Description of benefits: Responses that refer to explaining possible benefits to participation (e.g., "Benefits…", "..the benefits of the study")	3.4
Description of risks: Responses that refer to explaining possible risks to participation (e.g., "If the study is going to involve risk such as photos that may trigger a response", "…you have to be given information about potential risks…")	28.3
Confidentiality: Responses that refer to how data will be handled, such as whether the data will be deidentifiable, anonymous etc. (e.g., "…privacy practices…", "…what will be done with your information", "limits to confidentiality…")	17.7
Contact information: Responses that refer to including information about the researchers and/or IRBs, including their contact information	11.3
Study demands: Responses that refer to inclusion or exclusion criteria for the study, outside of method-related information (e.g., "…age allowed to participate…", "…what qualifications you need to have"	7.2
Mental health service information: Responses that refer to including directions to mental health services, mental health support, helplines etc. (e.g., "…provide ways to contact help if you are upset by something during the study…")	3.0

Funding of research: Responses that refer to overall research funding, individual funding of researchers, and/or researcher affiliations (e.g., "…the sponsor of the study…")	0.4
Compensation: Responses that refer to informing participants about compensation (e.g., "…what compensation I will be offered…")	1.9
Unsure of information: Responses that indicate the participant does not know what information they should be provided with (e.g., "unsure", "Well, being absolutely honest I have no idea")	1.9
Research outputs: Responses that refer to how the data will be used (e.g., "…what will be done with the results…")	16.2
Data storage: Responses that refer to data storage and/or issues related to data storage (e.g., "…how my information will be stored…")	6.4
Approval by IRB: Responses that refer to the research needing to be approved by an IRB (e.g., "…approved by an ethical organisation", "ethics approval number")	5.7
Q2: According to current ethics guidelines, what do you know your rights are as a participant?	
Unclear response: Responses that do not make sense or answer the question	3.8
Agreement: Responses that indicated participants knew what their rights were (e.g., "Mostly, yes")	1.1
Withdraw from participation: Responses that refer to withdrawing from participation at any point and/or choosing not to answer certain questions (e.g., "I can quit at any time", "I am allowed to withdraw from the study at any point")	81.9
Withdraw data from study: Responses that refer to withdrawing data from a study (e.g., "I am able to request that my data be remove or not used")	6.8
Informed consent: Responses that refer to the overall informed consent process, for instance receiving a consent form or reading a consent form for more information on rights (e.g., "They should ask for my consent to participate in the study", "…people need to be provided consent in order to participate")	23.1
Data storage: Responses that refer to data storage and/or issues related to data storage (e.g., "…how my information will be stored…")	1.1
Voluntariness: Responses that refer to not feeling coerced or participation being a voluntary choice (e.g., "…to participate is voluntary", "I know that it is voluntary")	10.2
Confidentiality: Responses that refer to how data will be handled, such as whether the data will be deidentifiable, anonymous etc. (e.g., "…privacy practices…", "…what will be done with your information", "limits to confidentiality…")	29.8
Contact information: Responses that refer to including information about the researchers and/or IRBs, including their contact information	3.0

Methods: Responses that refer to having the right to know what they will need to do in a study (e.g., "To be told what you will be asked to do in the study", "…what you will be asked to do if you are in the study")	5.3
Violation of rights: Responses that refer to information that is in opposition to participant's rights (e.g., "There are no rights", "…if I do complete a study then any information I give can be used by the researchers in whichever way they desire")	1.1
Inconsistent with rights: Responses that refer to an aspect of participant's rights that varies from study-to-study (e.g., "I will be kept anonymous", "…anonymity will be maintained")	12.5
Debriefing information: Responses that refer to debriefing procedures if deception was used (e.g., "debriefing", "you must be debriefed following the study")	10.6
Harm minimisation: Responses that refer to researchers protecting participants from harm (e.g., "You should be protected from harm…", "…protection of wellbeing")	17.0
Unsure of rights: Responses that refer to not knowing what rights they have (e.g., "No", "I don't really know", "not really")	3.0
Q3: According to current ethics guidelines, what do you know you can do if you have concerns about psychological research studies?	
Unclear response: Responses that do not make sense or answer the question	4.2
Contact information provided: Responses that refer to using the contact information, usually for researchers, IRBs, and/or topic coordinator, provided	81.1
Contacting employer: Responses that refer to contacting the organisation/crowdsourcing platform (e.g., "Contact the…company that advertised the study")	3.8
Unsure: Responses that refer to not knowing what to do (e.g., "No", "No idea")	7.9
Action other than those already mentioned (e.g., using contact information provided): Responses that refer to other actions relevant to consent (e.g., "withdraw", "withdraw without consequences")	30.9
Q4: What do participants want to change, if anything, about current consent guidelines?	
Unclear response: Responses that do not make sense or answer the question	3.4
No change: Responses that indicate participants do not want to change current guidelines (e.g., "nothing I would add", "no, I do not wish to change anything", "They seem to be very well covered and I don't have any issues with them")	60.8
More detail on aspects of consent that already exist: Responses that refer to providing more information about some aspect of consent (e.g., "It would be better to have clearer language around the purpose of the study…more details should be given", "Sample questions and if there will be writing involved", "…should always clearly state if there's potential for harm in the study")	4.2

Improved risk information: Responses that refer to including and/or making risk information more obvious (e.g., “I would want greater transparency on things like risks”, “I’ve been shown videos/photos of gruesome scenes – mangled corpse, tortured animals with absolutely no warning”, “…disturbing images must be preceded by warnings – if this is already the case then I def have taken studies that do not follow the guidelines”)	2.3
Presentation of consent information: Responses that refer to improving consent form presentation (e.g., “I think most people skim over these consent forms, so I think it would help if the important parts were in bold face type and the pertinent information be more noticeable in some way”, “I would only like for the information to be given in a manner as succinct and un-legalistic as possible”)	0.4
Change that is already enacted by guidelines: Responses that refer to changing an aspect of consent that should already be enacted (e.g., “A true timeline of how long it might take and a number for the ethics board”, “Many European researchers have no IRB listed”, “I would definitely like to see the amount of time expected”)	5.7
Referral to mental health services: Responses that refer to including referral to mental health services (e.g., “…if a person is triggered by a study there should be resources linked for mental health”)	2.3
Removing parts of consent that current exist: Responses that refer to removing parts of consent that are currently used (e.g., “I don’t see the need to provide potential benefits other than the compensation amount”, “I would drop all of the ethics guidelines…”, “I think you should remove IRB information since those are usually fake anyway”)	3.0
Did not respond to question: Responses that were left blank	20.8
Unsure: Response indicates person is unsure whether anything should change (e.g., “I am not sure”)	0.8
Improving understanding of rights: Responses that refer to improve participant’s understanding of rights (e.g., “To improve it maybe make the participant more aware of their rights because I was a little bit unsure”)	1.1
Viewing study results: Responses that refer to wanting to see study results and/or publication (e.g., “I believe the place of publication should be mentioned in the guidelines”)	2.3
Deceit and debriefing: Responses that refer to including debriefing information and/or strategies to address when deceit is used (e.g., “I would like there to be a debriefing statement after the study is done…”, “I would like the guidelines to include a section before taking the study that states whether or not information told to participants in the study could potentially be false.”)	1.9

Q1: According to Current Ethics Guidelines, What Information do you Know you Must be Provided About Psychological Studies Before Participating? Approximately half of participants mentioned critical consent components such as: methods (54.3%), study purpose (41.9%), and participant rights (e.g., right to withdraw from study; 34.7%). Other participants reported knowing they must be provided with information regarding: informed consent (31.3%), potential risks (28.3%), confidentiality (e.g., whether data will be deidentified; 17.7%), and potential research outputs (16.2%). Some participants identified that they must be informed: relevant contact information (11.3%), study demands (7.2%), data storage (i.e., how data will be stored; 6.4%), IRB approval (5.7%), and benefits (3.4%). Few participants reported having to know about: contact information for relevant support services (3%), compensation (1.9%), and research funding (0.4%). Some participants reported that they were unsure what information they should receive (1.9%); several responses were unclear and therefore not coded (8.7%).

Q2: …What do you Know Your Rights are as a Participant? Most participants reported that they knew they had the right to withdraw from participation (81.9%). Approximately one quarter of participants indicated that they had the right to confidentiality (29.8%) and informed consent (23.1%). Some participants reported that they had the right to: harm minimisation (e.g., to not be harmed; 17%), debriefing information if deception was used (10.6%), voluntariness (e.g., not feel coerced; 10.2%), and to withdraw their data from a study (6.8%). A minority also reported having the right to: know how data will be used (e.g., research outputs; 5.7%), method information (5.3%), contact information for researchers and/or IRBs (3%), and know how their data will be stored (1.1%). Of note, 12.5% of participants reported information inconsistent with their rights (e.g., remaining anonymous) and 1.1% reported information that was directly in violation of their rights (e.g., believing they had no rights or that they could not withdraw from participation). A further 3% of

participants indicated they were unsure what their rights were and 1.1% reported agreement with the idea they knew what their rights were. Some responses were unclear and thus not coded (3.8%).

Q3: …What do you Know you can do if you Have Concerns About Psychological Research Studies? Most participants indicated that they knew they could contact researchers, IRBs, and/or relevant university personnel if they had concerns about a psychological research study (81.1%); participants also reported actions other than contacting relevant people/organisations (e.g., withdrawing from participation; 30.9%). Some participants reported contacting the relevant company/organisation as an option if they had concerns about a psychological research study (3.8%), while others reported that they were unsure what to do (7.9%). Some responses were unclear and were not coded (4.2%).

To summarise, our results have three critical implications. First, undergraduates have some understanding of what information they should receive prior to participating. Specifically, basic knowledge was present for some critical consent components (e.g., methods, purpose, and rights), yet lacking in others (e.g., informed consent, risks, confidentiality, research outputs). Second, most undergraduates knew they could withdraw from participation if required, indicating strong understanding of this critical participant right. While some participants cited two other important rights (i.e., confidentiality and informed consent), few participants reported knowing their other rights. In fact, some participants reported information that was inconsistent with their rights, indicating that they may be agreeing to participate in studies without understanding the ramifications for data handling, storage, etc. For example, participants may assume their data is completely anonymous when it could be re-identifiable by researchers and personnel associated with the project. Such a discrepancy in understanding could lead participants to feel deceived or like they cannot trust researchers. Third, most undergraduates know they can contact relevant personnel if they

have concerns about psychological research studies. Some participants also indicated useful actions other than contacting relevant people, like withdrawing from the research if they were concerned about a study.

Pre-Existing Knowledge Statements. Next, we examined participant responses to our 15 consent statements; see Table 5.5 for descriptive statistics and consent statements listed in full. Overall, undergraduates showed a good understanding of consent guidelines: they rated nine ethics statements as "definitely true" (i.e., > 5, where *6 = Definitely true*), including consent components such as voluntariness, methods, participant rights, and risks; and four statements as somewhat true (i.e., > 4) for purpose, confidentiality, incentives, and benefits (note $M = 3.99$ so we include here) components.

Table 5.5

Descriptive Statistics for Pre-Existing Knowledge and Preferences Measures

Measure	Consent Component	*Mean*	*SD*	*n*
Guideline Specific Pre-Existing Knowledge				
1. "The consent form must provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate."	Voluntariness	5.30	1.08	265
2. "The consent form must provide me with sufficient information and adequate understanding of the research study to make a voluntary decision about participating."	Voluntariness	5.54	0.83	265
3. "The consent form must provide me with an adequate understanding of the study's purpose."	Purpose	4.86	1.51	265
4. "The consent form must provide me with an adequate understanding of the methods (e.g., "answering questionnaires") that will be used in the study."	Methods	5.01	1.27	264
5. "The consent form must include the expected duration of the study."	Methods	5.19	1.14	265
6. "The consent form must provide me with information about declining to participate, including withdrawing from the research after participation has begun."	Participants Rights	5.61	0.82	265
7. "The consent form must include contact details for researchers and Institutional Review Boards (i.e., ethics committees) should I have any complaints."	Participants Rights	5.17	1.25	265
8. "The consent form must provide me with an adequate understanding of what potential personal benefits are involved in participating."	Benefits	3.99	1.67	265
9. "The consent form must provide me with an adequate understanding of what potential community benefits are involved in participating."	Benefits	3.41	1.70	264
10. "The consent form must provide me with an adequate understanding of what potential risks are involved in participating."	Risks	5.59	0.75	265
11. "The consent form must warn me against participating if the study will be overly distressing (e.g., recalling a traumatic event)."	Risks	5.48	1.05	265

12. “The consent form must include information about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.59	0.91	265
13. “The consent form must include information about how the data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.92	1.44	265
14. “The consent form must explain what compensation I will receive.”	Incentives	4.53	1.50	264
15. “The consent form must include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.70	1.82	264
Guideline Specific Preferences				
1. “I expect that the consent form will provide me with enough information and understanding that I can make a voluntary decision about participating.”	Voluntariness	5.78	0.63	265
2. “I expect that the consent form will provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate.”	Voluntariness	5.50	1.00	265
3. “I expect to be informed about the study’s purpose.”	Purpose	4.89	1.50	265
4. “I expect to know what the study’s procedure is.”	Methods	5.00	1.28	265
5. “I expect to know what types of questions I will answer during participation (e.g., I expect to see sample questions prior to deciding to participate.”	Methods	3.46	1.87	265
6. “I expect to know the expected duration of the study.”	Methods	5.34	0.93	265
7. “I expect to be told what my rights are as a participant on the consent form (e.g., that I can withdraw from participating at any time).”	Participants Rights	5.79	0.53	265
8. “I expect to have contact information (e.g., email telephone number) for the researchers and relevant ethics board).”	Participants Rights	5.28	1.16	265
9. “I expect that I can contact the researchers and/or relevant ethics board if I have concerned about the research study.”	Participants Rights	5.49	0.83	265
10. “I expect that all possible benefits of participating are listed on the consent form.”	Benefits	3.96	1.67	265
11. “I expect that no benefits are listed on the consent form.”	Benefits	2.39	1.70	265

12. “I expect that all possible risks of participating are listed on the consent form, including risks that are unlikely to occur”	Risks	5.15	1.31	265
13. “I expect that no risks are listed on the consent form.”	Voluntariness	0.95	1.61	265
14. “I expect to be told about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.50	0.95	264
15. “I expect to be told how that data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.83	1.42	265
16. “I expect to be told what compensation I will receive.”	Incentives	4.48	1.42	265
17. “I expect the consent form to include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.90	1.87	265

Undergraduates demonstrated less knowledge in relation to benefits: rating one statement as "neither true nor false" (> 3), in addition to declarations of interest: rating one statement as "somewhat false" (> 2, where *0 = Definitely false*).[30] Similar to our findings in Study 2a, these consent guideline statements may represent a lesser known area of consent for undergraduates and/or areas that they do not tend to view or notice on consent forms.

Much like Study 2a, if we look only to the pre-existing knowledge *statement* data, we might conclude that undergraduates have strong knowledge for consent. However, the open-text data showed their overall understanding of consent practices was much lower. Hence, based on these data, we estimate undergraduates' baseline knowledge of consent as low-to-moderate, consistent with similar consent literature (e.g., Perrault & Nazione, 2016).

What are Participants' Consent Preferences (i.e., What do They Expect From IRBs and Researchers)?

Next, we examined undergraduates' *preferences* for consent practices (see Table 5.5). Participants reported strong agreement (i.e., > 5, where *6 = Strongly agree*) with nine preference statements across six consent components: voluntariness, methods, participant rights, confidentiality, and risks; and somewhat strong agreement with three preference statements (i.e., > 4), for components such as study's purpose, confidentiality, and incentives. Participants indicated that they neither agreed nor disagreed (i.e., > 3) with two consent preference statements on two components: methods and benefits. These results suggest that undergraduates have strong preferences *in favour* of these consent practices (e.g., voluntariness, methods, risks).

Participants indicated somewhat strong (i.e., > 2, where *0 = Strongly disagree*) disagreement with two preference statements across two components: benefits and

[30] We repeated these analyses after removing participants who did not consent to answering the Criterion A question (n = 241). There was minimal difference between means (i.e., 0.01-0.50 change) and therefore we include results for the interested reader at: https://osf.io/ru8e5/.

declarations of interest. Specifically in terms of benefits, participant preference ratings indicated they want benefits listed on the consent form. Participants also reported strong disagreement with one risk statement, meaning that participants want risks listed on the consent form.[31] Regarding risk communication for undergraduates, their preference responses indicate they want all potential risks associated with participation reported at consent as opposed to no risks included at consent.

Thus, our results indicate that undergraduates want critical consent components to continue to form part of the consent process (e.g., methods, rights, confidentiality, risks, purpose, and incentives). Because undergraduates indicated a strong preference toward voluntariness, these critical consent components should continue to work together to help participants feel they have enough information to make an informed decision regarding participation; a decision that is also free of coercion. Of note, several consent components—including method, risk, and confidentiality-related information—are parts of consent that undergraduates seem more likely to read first (Douglas et al., 2021). Indeed, future research could use eye-tracking technology to confirm which sections of informed consent participants engage with, building upon prior research that uses eye-tracking to assess consent behaviour more generally (e.g., how number of informed consent pages affects reading; Rosa et al., 2019; Russell et al., 2019).

Although disclosing any *potential risk* associated with participation—whether these risks are significant or minor—may present other ethical issues (e.g., warning people of a negative outcome may inadvertently cause that outcome to occur [nocebo effect]; Abu-Rus et al., 2019), undergraduates report a strong preference for including all risks during the consent process. Indeed, this consent preference is helpful for researchers and IRBs to consider when

[31] We repeated these analyses after removing participants who did not consent to answering the Criterion A question (n = 241). There was minimal difference between means (i.e., 0.01-0.50 change) and therefore we include results for the interested reader at: https://osf.io/ru8e5/.

formulating consent forms specific to undergraduates. One way to honor undergraduates' preferences and balance against potential nocebo effects is to closely consider *how* risk information is presented. For instance, recent research suggests that applying *framing effects* (e.g., "8 out of 10 people will *not* experience side-effects") to risk information presentation may attenuate nocebo effects (e.g., Barnes et al., 2019; Faasse, Huynh et al., 2019; Webster et al., 2018). Exploring such presentation options within the context of psychological research consent forms may assist in balancing participant preferences with harm minimisation.

Finally, undergraduate preferences for consent highlight two potential areas of consent that may be shortened and/or not included. Undergraduates appeared indifferent about the idea of including sample questions (as part of a method explanation) or including community-related benefits. Therefore, for an undergraduate sample, researchers could provide a general method overview (e.g., view a film and answer questionnaires regarding emotions) and focus on benefits that are self-related (i.e., to the participant).

Do Participant Consent Preferences Differ Based on Prior Trauma-Exposure?

Here, we also examined whether participants' consent preferences differed based on prior trauma-exposure. Again, as per our sensitivity analysis, we could reliably detect significant effects at $d = 0.41$ and above. See Table 5.6 for descriptive and inferential statistics in full. Comparable to prior traumatic event exposure estimates in undergraduate samples (e.g., Frazier et al., 2009), a majority of our participants reported prior trauma-exposure (73.03%; no trauma-exposure = 26.97%).

Table 5.6

Descriptive and Inferential Statistics, Including Bayes Factors, for Pre-Existing Knowledge and Consent Preference Statement Group Comparisons

		Trauma-Exposed (*n* = 176)	Non-Trauma-Exposed (*n* = 65)			
Measure	Consent Component	*M(SD)*	*M(SD)*	*p*	*Cohen's d*	BF_{10}
Guideline Specific Pre-Existing Knowledge						
1. "The consent form must provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate."	Voluntariness	5.34 (1.06)	5.26 (1.02)	.628	0.07	0.18
2. "The consent form must provide me with sufficient information and adequate understanding of the research study to make a voluntary decision about participating."	Voluntariness	5.59 (0.81)	5.42 (0.90)	.185	0.20	0.39
3. "The consent form must provide me with an adequate understanding of the study's purpose."	Purpose	4.85 (1.53)	4.86 (1.52)	.946	0.01	0.16
4. "The consent form must provide me with an adequate understanding of the methods (e.g., "answering questionnaires") that will be used in the study."	Methods	4.88 (1.33)	5.28 (1.10)	.033	0.31	1.35
5. "The consent form must include the expected duration of the study."	Methods	5.16 (1.17)	5.14 (1.18)	.888	0.02	0.16
6. "The consent form must provide me with information about declining to participate, including withdrawing from the research after participation has begun."	Participants Rights	5.61 (0.81)	5.58 (0.81)	.806	0.04	0.16
7. "The consent form must include contact details for researchers and Institutional Review Boards (i.e., ethics committees) should I have any complaints."	Participants Rights	5.09 (1.39)	5.35 (0.89)	.079	0.21	0.42
8. "The consent form must provide me with an adequate understanding of what potential personal benefits are involved in participating."	Benefits	3.87 (1.74)	4.15 (1.66)	.265	0.16	0.28
9. "The consent form must provide me with an adequate understanding of what potential community benefits are involved in participating."	Benefits	3.21 (1.73)	3.85 (1.60)	.010	0.38	3.62

10. “The consent form must provide me with an adequate understanding of what potential risks are involved in participating.”	Risks	5.58 (0.77)	5.63 (0.65)	.633	0.07	0.18
11. “The consent form must warn me against participating if the study will be overly distressing (e.g., recalling a traumatic event).”	Risks	5.43 (1.08)	5.54 (0.85)	.474	0.10	0.20
12. “The consent form must include information about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.53 (0.99)	5.65 (0.82)	.393	0.12	0.22
13. “The consent form must include information about how the data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.91 (1.41)	4.75 (1.59)	.449	0.11	0.21
14. “The consent form must explain what compensation I will receive.”	Incentives	4.50 (1.50)	4.60 (1.50)	.646	0.07	0.17
15. “The consent form must include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.55 (1.84)	2.80 (1.69)	.349	0.14	0.24
Guideline Specific Preferences						
1. “I expect that the consent form will provide me with enough information and understanding that I can make a voluntary decision about participating.”	Voluntariness	5.77 (0.62)	5.82 (0.43)	.609	0.07	0.18
2. “I expect that the consent form will provide me with an understanding of reasonably foreseeable factors that might influence my willingness to participate.”	Voluntariness	5.45 (1.06)	5.63 (0.72)	.130	0.19	0.34
3. “I expect to be informed about the study’s purpose.”	Purpose	4.90 (1.44)	4.82 (1.59)	.702	0.06	0.17
4. “I expect to know what the study’s procedure is.”	Methods	4.94 (1.33)	4.95 (1.23)	.931	0.01	0.16
5. “I expect to know what types of questions I will answer during participation (e.g., I expect to see sample questions prior to deciding to participate.”	Methods	3.31 (1.87)	3.71 (1.84)	.145	0.21	0.43
6. “I expect to know the expected duration of the study.”	Methods	5.38 (0.89)	5.20 (1.06)	.240	0.19	0.34
7. “I expect to be told what my rights are as a participant on the consent form (e.g., that I can withdraw from participating at any time).”	Participants Rights	5.81 (0.53)	5.74 (0.54)	.378	0.13	0.23
8. “I expect to have contact information (e.g., email telephone number) for the researchers and relevant ethics board).”	Participants Rights	5.26 (1.15)	5.35 (1.07)	.573	0.08	0.18

9. “I expect that I can contact the researchers and/or relevant ethics board if I have concerned about the research study.”	Participants Rights	5.53 (0.77)	5.46 (0.90)	.537	0.09	0.19
10. “I expect that all possible benefits of participating are listed on the consent form.”	Benefits	3.87 (1.68)	4.03 (1.68)	.524	0.09	0.19
11. “I expect that no benefits are listed on the consent form.”	Benefits	2.44 (1.72)	2.37 (1.65)	.783	0.04	0.16
12. “I expect that all possible risks of participating are listed on the consent form, including risks that are unlikely to occur”	Risks	5.10 (1.36)	5.35 (0.94)	.099	0.20	0.40
13. “I expect that no risks are listed on the consent form.”	Voluntariness	1.00 (1.63)	0.78 (1.47)	.350	0.14	0.24
14. “I expect to be told about the limits of confidentiality (e.g., who will have access to my information).”	Confidentiality	5.46 (1.02)	5.52 (0.87)	.673	0.06	0.17
15. “I expect to be told how that data collected in the study will be used (e.g., for publications, at conferences).”	Confidentiality	4.77 (1.48)	4.89 (1.23)	.561	0.08	0.19
16. “I expect to be told what compensation I will receive.”	Incentives	4.51 (1.47)	4.42 (1.35)	.666	0.06	0.17
17. “I expect the consent form to include information about the amount(s) and source(s) of funding for the research.”	Declarations of Interest	2.82 (1.86)	2.86 (1.85)	.872	0.02	0.16

We ran a series of independent samples t-test and corrected for multiple comparisons (i.e., adjusted statistical significance: $p < .003$); we also report corrected values (i.e., unequal variances assumed) where Levene's test was violated. Overall, our analyses revealed that trauma-exposed and non-trauma-exposed participants had similar preferences, *p*s: .130 - .931, *d*s: 0.01 – 0.21. We also calculated Bayes Factors. Here, we found substantial evidence in favour of the null hypothesis (BF_{10}: 0.16 – 0.24), relative to the alternative hypothesis, for 13 preference statements, in addition to anecdotal evidence in favour of the null hypothesis—over the alternative hypothesis—for four preference statements (BF_{10}: 0.34 – 0.43). Finally, when considering our results from a traditional significance perspective (i.e., without correction for multiple comparisons), *none* of our analyses reached significance (i.e., $p < .05$).

Taken together then, our results indicate that overall, undergraduates have similar preferences for consent practices regardless of prior trauma-exposure. Importantly, undergraduates' preferences for the communication of risks during the consent process did not seem to differ based on trauma-exposure.

What do Participants Want to Change, If Anything, About Current Consent Guidelines? Just over half of our participants reported that they were content with current ethics guidelines (i.e., wanted no change; 60.8%; see Table 5.4). Some participants reported wanting various specific changes relating to: providing more detail (e.g., about researcher's qualifications; 4.2%), removing parts of consent that currently exist (3%), improving risk information (e.g., including more discussion of risks; 2.3%), seeing study results (2.3%), including mental health service referrals (2.3%), including explicit debriefing information when deceit is used (1.9%), improving understanding of rights (1.1%), and presenting consent information in a simplified way (0.4%). Additionally, 5.7% of participants reported changes that are already enacted in current guidelines (5.7%). Some participants did not respond to the question (20.8%) and other participants indicated they were unsure whether

guidelines should change (0.8%); the remaining responses were unclear and were not coded (3.4%).

Here, a substantial portion of participants indicated that they were currently satisfied with consent information. Although we did not code it as such, potentially the few participants who did not respond to the question were also satisfied with current guidelines (i.e., desired no change). Most participants requested changes to consent centred around consent information that—in line with current ethical guidelines—should already be enacted (NHMRC, 2018; Public Welfare Act, 2018). For example, information regarding risks, and information about how the study's results can be obtained (e.g., via publication of the results), already form parts of consent. Together, our undergraduate feedback suggests the highlighted consent information areas need to be more consistently employed by researchers/IRBs.

General Discussion

In two studies, we examined how effective current ethical guidelines are (i.e., from BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018) from the participant's perspective; specifically in trauma-exposed and non-trauma-exposed participants. Overall, we found that participants across both samples were generally satisfied with current consent guidelines (e.g., in terms of information provided) and expressed preferences that align with the current system (e.g., making consent information more consistent across IRBs/studies). Notably, there was a small yet consistent trend of participants reporting seemingly unethical behaviour from IRBs and/or researchers (e.g., inaccurate IRB information provided if at all provided). Thus, our study serves as a reminder to IRBs and researchers alike to engage in good faith with the consent process. Further, participants showed some—albeit limited—knowledge regarding consent information they know they should receive. Importantly, we found that

preferences and knowledge were *similar* across both samples, regardless of trauma-exposure. We interpret and discuss the implications of these findings below.

Notably, irrespective of prior trauma-exposure, participant preferences for consent were *similar,* particularly for core consent components (e.g., voluntariness, risks, methods etc). These similarities across both samples occurred despite variability between the samples (i.e., differences in perceived prior study experience, mean age, prior education, and gender distribution). Our finding contradicts areas of IRB and researcher apprehension regarding psychological trauma research (described in Jaffe et al., 2015; Newman et al., 2006). For instance, our data—two samples that both comprised at least two thirds of people reporting exposure to a Criterion A trauma—suggest people who have prior trauma-exposure do not warrant special precautions as part of the informed consent process. Recall that more than half of participants preferred no change to current ethical guidelines and *few* participants required drastic changes to meet their needs. Across both samples, several predominant suggestions for consent guideline improvement were also either already addressed in current ethical guidelines or specific to the sample-type and unrelated to prior trauma-exposure (i.e., MTurk worker preferences relating to pay). Indeed, our results suggest that trauma-exposed participants are satisfied with current ethical guidelines and do not necessitate procedures specific to an ethically "vulnerable" population (Newman & Kaloupek, 2009), as might be applied in cases of children, etc (NHMRC, 2018). In fact, most participants' feedback about consent related to actions that researchers and/or IRBs could implement immediately (e.g., ensuring consistency across guideline implementation, providing more detail). Together then, for undergraduate and crowdsourcing samples, our results suggest that prior trauma-exposure does not impact participants' consent preferences.

Turning to preferences more generally, both samples expressed some unique requests. For instance, MTurk workers highlighted issues around pay and concerns about accurate

completion times. And undergraduates expressed that most—if not all—potential associated risks of participation should be included on consent forms. Yet, our samples—despite differences in characteristics (e.g., education, age distribution)—expressed several similar consent preferences (e.g., including information at consent that should already be included, such as risk, data use [including how to access study findings], and withdrawal information). Our findings thus do not fit with some prior research regarding psychological consent form improvement (e.g., Douglas et al., 2021; Perrault & Keating, 2018), though this prior research occurred in non-psychologically sensitive areas. Hence, future research should examine the efficacy of some participant suggestions (e.g., bolding risk-related information)—provided here—*within* a psychologically *sensitive* research context.

Moreover, our preference findings do not support some prior, well-intentioned, researcher suggestions to remove parts of consent or shorten the length of forms (Perrault & Keating, 2018; Perrault & Nazione, 2016). However, we must consider how our sample's consent preferences fit with prior research on consent behaviour that shows participants generally do not read/skim consent forms, even when alternative consent forms are offered (e.g., shorter form length, bolding important information; McNutt et al., 2008; Perrault & Nazione, 2016; Ripley et al., 2018). Here, we argue that it is more important for participants to *know* they have access to all relevant consent information, even if they *choose* not to engage with it. Indeed, prior research found 41.8% of participants said they would read a consent form if they felt it concerned an important issue to them, but this importance did not typically extend to psychological research consent forms (Perrault & Keating, 2018). Perhaps then, if we know amendments to consent do not seem to boost consent engagement, but we want *informed* participants, we should continue to focus our efforts on delivery format. For instance, prior research found having an experimenter present while participants engaged in the consent process meant participants were more likely to read the form (Ripley et al., 2018).

Therefore, future research should continue to investigate effective delivery formats to balance participant preferences (i.e., critical consent components they want included) against their behaviour. One example is to include more interactive elements at consent to boost attention (Geier et al., 2021).

Regarding participants' pre-existing knowledge of consent, our data revealed that participants had minimal-to-moderate existing knowledge. We note differences between our measures of pre-existing knowledge. One explanation for this discrepancy is that our consent statements reminded participants of other aspects of consent they had forgotten about—during free recall—and so they rated these aspects as true. Alternatively, perhaps participants engaged in socially desirable responding (e.g., participants already consented to participate so perhaps they wanted to be seen as "good" by responding in line with what they thought we would want them to know; Crowne & Marlowe, 1960; Rasinski et al., 1999). Regardless, just as prior consent research has reported participants' low-to-moderate consent form comprehension (e.g., Ripley et al., 2018), we find a similar pattern of results here. One counter explanation for participants choosing not to read and/or skim consent forms is that they have strong basic knowledge of psychological consent practices and therefore do not feel they need to closely engage with consent. Yet, our findings do not support this explanation. Rather, our findings add to the idea that many participants consent to psychological research studies without being properly *informed,* albeit because they likely believe the information is not important enough to read (Perrault & Keating, 2018).

We originally suspected our samples may differ in their knowledge results because of differences in study completion experience. But that was not the case despite observable differences in reported experience (i.e., crowdsourced = very experienced with median of 5000 studies, undergraduates = somewhat experienced with $M = 5.43$). Our data therefore provide further evidence that removing parts of consent or shortening consent may not be a

viable solution moving forward. Participants do not seem to holistically know what they should be told—and to what standard—at consent, hence removing existing information at consent may mean they are disadvantaged by being less *informed* (i.e., less access to information they do not know they should have). Moving forward, baseline knowledge for participants could be improved by requesting they complete a standardised consent training course (i.e., informing them of their rights, key elements in consent that may differ between studies, and key elements to focus on when reading consent forms). Afterward, participants could be provided with a handout that helps them navigate consent (e.g., what different terms mean). This suggested approach would provide participants with a foundation for consent and equip them with the skills to identify when consent information is not adequate—as was sometimes reported here by participants citing inclusion of consent information that should already be enacted.

Our study has limitations. We did not collect information relating to current psychopathology (e.g., PTSD symptomology, depression, anxiety) or details of prior trauma-exposure (e.g., type of event, repeated). We chose not to collect such data because we wanted to capture all participants' consent views without changing the study into a *trauma-related* study itself (e.g., by having to include trauma questionnaire information in the advertisement). However, it is possible that participants who have experienced *certain types* of traumatic events differ in their consent preferences. For instance, some researchers have raised concerns about people who have experienced interpersonal violence and whether these participants may feel coerced during the consent process (Newman & Kaloupek, 2009). Thus, gathering participant consent preferences from specific trauma populations would enrich our understanding of participant consent needs. Additionally, our sample's high reported trauma-exposure rates may raise questions about how meaningful it is to divide participants by trauma-exposure alone. Yet, this limitation provides additional support for the idea that IRB

concerns regarding trauma-related research are likely unfounded. If psychological samples comprise a majority of trauma-exposed people, and these participants have similar preferences for consent procedures as non-trauma-exposed participants, it is not necessarily meaningful for IRBs to differentiate on trauma-exposure alone either. Future research however should investigate consent preferences based on additional psychopathology measures (e.g., PTSD symptomology, trauma-exposure type).

In Study 2a, crowdsourced participants reported completing an average of over 14,000 studies. One possibility is that this estimate reflects bot responding. However, we believe this possibility is unlikely because we used several strategies to maintain data quality and minimise bot/server farmer responding (see https://osf.io/gjryt for strategies in full). Importantly, we used Cloud Research approved participants (i.e., who passed Cloud Research's attention and engagement measures; Hauser et al., 2023) with settings such as: blocking suspicious geocode locations and limiting approval rating to 95%-100%. An alternative explanation for participants' varied frequency estimates is that they used different decision-making strategies to estimate their prior study completion (e.g., breaking down approximately how studies they complete daily and multiplying by their imagined lifetime completion rate; e.g., Brown, 1995). Some of these strategies may have been effective, while others may have been biased by decision-making heuristics (e.g., relying on information that comes to mind quickly and with ease; e.g., Dale, 2015), resulting in overestimation. Indeed, the study frequency data was strongly positively skewed, with outliers present, and is similar to prior studies investigating MTurk (Cloud Research) use in terms of large standard deviations for yearly estimates (e.g., Douglas et al., 2023) and more than half of participants reporting they use MTurk for more than 8 hours per week (Peer et al., 2022). Our data highlight the importance of measuring participants' prior study completion frequency, and

other related topics, when relying on crowdsourced data. Doing so will help researchers understand this unique population.

Here, we strictly assessed information that is provided to participants during the consent process and not other areas of consent (e.g., whether people *actually* withdraw from participation versus saying they know how to, coercion). Although some prior consent research shows that people exposed to traumatic events can refuse participation and/or withdraw from sensitive psychological research (Brabin & Berah, 1995; Hlavka et al., 2007), it would be useful for IRBs and researchers to explore other participants' views and preferences on different operationalisations of consent. Here, we focused on two commonly used sample types within psychological research (i.e., crowdsourced and undergraduate students, albeit in two different Western countries) and thus our findings are specific to these sample types. Future research should address whether participant preferences found in the current study hold across different samples (e.g., US undergraduate students, clinical populations, community members), although we note that US undergraduates typically appear to be viewed as generalisable to other undergraduate populations. Finally, the consent statements participants responded to were developed based on Western ethical guidelines and therefore the results here cannot be generalised beyond this context.

Together, our research provides evidence on crowdsourced and undergraduate participants' views and preferences for consent practices, particularly where sensitive research is concerned. Notably, we found similar findings for consent views among crowdsourced and undergraduate participants, irrespective of trauma-exposure. Thus, we hope these data can act as both a guide and reminder for IRBs and researchers when formulating consent processes for these samples. And, that these data serve as a basis for further research into how we can address ethical issues relating to consent for our participants.

Supplementary Files

Study 2a

Table S4

Pairwise Comparisons of Factors Influencing Decision to Participate

Comparison	*Mean Difference*	*p*	*d*	95% CI
Financial compensation				
Financial vs. Science	0.53	.001	0.44	[0.23, 0.83]
Financial vs. Mental Health	2.00	.001	1.25	[1.57, 2.43]
Financial vs. Interesting	0.32	.025	0.28	[0.02, 0.62]
Financial vs. Use of Time	0.63	.001	0.51	[0.01, 0.40]
Contributing to science				
Science vs. Mental Health	1.47	.001	0.90	[1.17, 1.77]
Science vs. Interesting	-0.21	.027	0.17	[-0.40, -0.01]
Science vs. Use of Time	0.10	1.00	0.09	[-0.12, 0.33]
Help my mental health				
Mental Health vs. Interesting	-1.68	.001	1.05	[-1.96, -1.40]
Mental Health vs. Use of Time	-1.37	.001	0.83	[-1.69, -1.05]
Studies are interesting				
Interesting vs. Use of Time	0.31	.001	0.25	[0.12, 0.50]

Study 2b

Table S5

Factors Influencing Decision to Participate in Psychological Research Studies

Comparison	*Mean Difference*	*p*	*d*	95% CI
Studies are interesting				
Interesting vs. Science	0.25	.046	0.20	[0.002, 0.49]
Interesting vs. Good use of time	0.81	.001	0.67	[0.61, 1.00]
Interesting vs. Mental health	1.42	.001	1.07	[1.16, 1.67]
Interesting vs. Financial	2.28	.001	1.53	[1.94, 2.62]
Contributing to science				
Science vs. Good use of time	0.56	.001	0.49	[0.29, 0.83]
Science vs. Mental health	1.17	.001	0.89	[0.88, 1.47]
Science vs. Financial	2.03	.001	1.37	[1.67, 2.40]
Help my mental health				
Mental Health vs. Good use of time	-0.61	.001	0.39	[-0.88, -0.35]
Mental Health vs. Financial	0.86	.001	0.54	[0.52, 1.20]
Good use of time				
Good use of time vs Financial	1.47	.001	0.90	[1.10, 1.84]

Table S6

Participant Percentage Response for How Long Participants Have Been Completing Psychological Studies for (Undergraduates)

Experience Descriptor	Percentage (%)
1 year (2)	15.3
6 months (5)	8.8
Since the start of the year (9)	8
No amount of time/I haven't previously completed studies (0)	7.3
One semester (3)	5.7
2 years (14)	5.4
1 month (21)	5.4
Less than 24 hours, e.g., "1 hour", "2 hours", "9 hours" (19)	4.6
2 weeks (11)	4.2
1 week (4)	3.4
Less than 7 days (24)	3.4
3 months, including "a few months" (1)	3.1
3 years (23)	3.1
Unclear response, e.g., "not long, 20" (8)	2.7
"Just started", "just beginning" etc. (16)	2.7
2 months (22)	2.3
4 weeks (20)	1.9
4 months (7)	1.5
7 months (12)	1.5
3 weeks, including a few weeks (13)	1.5
8 months (25)	1.5
5 months (6)	1.1
Since high school (18)	1.1
7 weeks (29)	1.1
2.5 years (15)	0.8
1.5 years (17)	0.8
3 weeks (27)	0.8
10 months (26)	0.4
6 weeks (28)	0.4

Chapter 6: Research Question Three: Are Informed Consent Risk-Warnings Contributing to Negative Outcomes for Participants in Psychological Trauma-Related Research?

Informed consent risk-warnings communicate potential risks (or side-effects) associated with participation to participants. They usually feature in consent procedures for psychological trauma-related research because of the perceived risks attached to this research (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; see Chapter 1 for discussion). Risk-warnings serve a dual purpose: They signal respect for participant *autonomy* (e.g., by providing people with relevant information to make an informed decision) and act as one—among several (e.g., providing mental health hotlines, debriefing)—harm mitigation strategies in trauma-related research (e.g., Becker-Blease & Freyd, 2006). Hence, risk-warnings also help uphold the *non-maleficence* (i.e., cause no harm) ethical principle.

Although well intentioned, some researchers have raised concerns that risk-warnings may have the opposite effect—i.e., increasing rather than decreasing harm (Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Bridgland & Takarangi, 2021; Loftus & Fries, 2008; 1979; Loftus & Teitcher, 2019). Researchers have pointed out that consent risk-warnings that overstate risk of harm—and thus are more likely to use inflammatory or harsh language—might create an expectation of risk or symptoms (Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Bridgland & Takarangi, 2021). Similarly, this risk-warning scenario may cause a "self-fulling prophecy" (Loftus & Teitcher, 2019), whereby "overly alarming language may create anxiety for participants", leading them to experience anxiety (Becker-Blease & Freyd, 2006, p. 219). Therefore, participants may be harmed via a strategy meant to protect them.

Ethically, herein lies a conundrum. To show respect for autonomy, participants need to receive enough information via informed consent to determine whether participation is suitable for them; that is, they must be able to provide voluntary and informed consent (e.g.,

NHMRC, 2023). But, if risk-warnings themselves increase harm, then this process would violate the non-maleficence principle. It is thus important to investigate whether the informed consent risk-warnings used in psychological trauma-related research cause negative outcomes—or nocebo effects—for participants.

To conceptualise *negative outcomes* arising from consent risk-warnings, it is first necessary to understand the nocebo phenomenon.

What are Nocebo Effects?

"Help me, I took all my pills", Mr A stated before collapsing in front of emergency department staff (Reeves et al., 2007). Mr A was part of a drug trial to treat depression, and after his girlfriend broke up with him, he ingested 29 capsules (Reeves et al., 2007). Staff were obviously concerned about Mr A: He was pale and sweating profusely, his blood pressure was low and heart rate elevated (Reeves et al., 2007). Despite treatment, Mr A did not improve. But a physician from Mr A's drug trial soon informed hospital staff that Mr A was in the *placebo* arm of the drug trial, meaning he had ingested 29 sugar capsules (Reeves et al., 2007). Within 15 minutes of hearing the news, Mr A's symptoms subsided (Reeves et al., 2007). Mr A's curious case is an example of the nocebo phenomenon.

Sometimes considered the "dark side" of placebo effects (i.e., positive outcomes caused by people's positive expectations about their health; Colloca & Barsky, 2020), nocebo effects originate from the medical field (Hahn, 1997; Planès et al., 2016). Contemporary definitions converge on the idea of negative expectations; when people expect a negative outcome, this expectation manifests—or worsens—the negative outcome (Bartels et al., 2014; Benedetti et al., 2007; Faasse, Helfer et al., 2019; Häuser et al., 2012). In Mr A's case, for instance, suggestions about potential medication side-effects may have led Mr A to expect to experience these side-effects, leading to these side-effects occurring.

Nocebo Effects in Action: Medical-Based Outcomes

There is evidence for nocebo effects across various clinical conditions (see Colloca, 2024 for review), including Parkinson's disease (e.g., Benedetti et al., 2003; Mercado et al., 2006; Pollo et al., 2002), nausea in patients receiving chemotherapy treatment (e.g., Colagiuri & Zachariae, 2010), and asthma (e.g., Jaén & Dalton, 2014; Luparello et al., 1970). Nocebo effects have also extensively been documented for pain (see Petersen et al., 2014 for meta-analysis). In one example, women told they were "…going to feel a big sting and burn in your back now, like a big bee sting…" during anaesthesia administration reported significantly more pain than women told they would be comfortable (Varelmann et al., 2010, p. 868).

Another line of evidence comes from empirical work that informs participants about different side-effect information, though not during the informed consent process (e.g., Barnes et al., 2023; Mondaini et al., 2007; Varelmann et al., 2010). In one example, participants exposed to negatively framed side-effect information (i.e., emphasising the likelihood of experiencing side-effects; "18 out of 100 people will experience headaches") *and* positively framed side-effect information (i.e., highlighting the likelihood of not experiencing side-effects) were more likely to experience nocebo effects for symptoms presented as side-effects, compared to a control condition (Faasse, Huynh et al., 2019). In another example, online participants exposed to side-effect information about low frequency noise reported more side-effects than participants exposed to no side-effect information. This finding held when side-effect information was delivered directly via listed side-effects and socially via reports from other people, and replicated in a second study (Barnes et al., 2023). In a final example, participants who received side-effect information about nausea, prior to entering a virtual reality setting, were more likely to report experiencing cybersickness side-effects than participants not exposed to side-effect information (Mao et al., 2021).

A recent systematic review and meta-analysis shows the magnitude of nocebo effects across different health-related outcomes (Rooney et al., 2024). Of 130 health-related nocebo effect studies, there was an overall moderate nocebo effect (g = 0.52), and medium effect sizes for somatic symptoms (versus other health-related outcomes), including headaches (g = 0.63), nausea (g = 0.62), and pain (g = 0.59). Sample type also mattered: nocebo effects were larger in studies involving clinical (g = 1.22) versus healthy samples (g = 0.51). Moreover, nocebo effects were larger for outcomes measured via self-report, compared to more objective means (e.g., behavioural outcomes). Hence, nocebo effects are a robust phenomenon that varies in magnitude, depending on sample and measurement type.

Nocebo Effects in Action: Psychological-Based Outcomes

Because I am concerned with risk-warnings and potential *psychological* nocebo effects, one critical question is: do nocebo effects occur for psychological outcomes? Although the literature is small (e.g., Rooney et al., 2024), the tentative answer is yes (e.g., Geers et al., 2021). These psychological outcomes diverge into two main categories: cognitive (e.g., learning and memory) and affective outcomes.

Cognitive Outcomes. Previous research on cognitive nocebo outcomes shows mixed findings. In one example favouring nocebo effects, participants told negative information about the effect of smelling an odour (e.g., odour may impair cognitive performance)—prior to completing a cognitive task—had slower reaction times (i.e., nocebo effect) compared to participants given no information about the odour (Colagiuri et al., 2011). Contrastingly, participants in Winkler and Hermann's (2019) experiment who received either positive (e.g., performance will improve) or negative (e.g., performance will worsen) suggestions regarding cognitive performance, coupled with an inert nasal spray, showed no difference on *objective* cognitive test outcomes (e.g., on alertness, working memory). However, in this study, participants who received a negative suggestion *expected* their cognitive performance to be

impaired and vice versa. Similarly, Blokland (2023) found that participants given positive (e.g., performance will improve) or negative (e.g., performance will worsen) suggestions about cognitive performance did not differ on *objective* cognitive performance measures (i.e., via Tower of London, n-Back tasks). However, participants assigned to the nocebo condition reported they subjectively felt they had performed more poorly on the cognitive tests and had more difficulty concentrating. In fact, Rooney and colleagues' (2024) systematic review and meta-analysis comprising ten cognitive experiments found no evidence of nocebo effects for cognitive outcomes ($g = 0.10$). As the authors noted, this finding may be because cognitive outcomes vary between experiments (e.g., memory, executive functioning, fatigue), meaning the effect may exist for some cognitive outcomes and not others. Nevertheless, this extant research indicates that participants' expected—or subjective evaluation—of their cognitive performance is amenable to suggestion.

There is also related literature that does not aim to examine nocebo effects specifically, but nonetheless provides some evidence for them. There may be other examples, but in one study measuring cognitive outcomes, participants told their drink was alcoholic—when it was really tonic water—were more vulnerable to misinformation during an eyewitness memory experiment, than people who were told their drink was tonic water (Assefi & Garry, 2003). Here, the suggestion of alcohol was enough to create an expectancy in line with people's broader social expectancy about alcohol consumption; perhaps poorer concentration, which created vulnerability to misinformation. Therefore, nocebo effects for cognitive outcomes are possible, depending on how the cognitive outcome is operationalised.

Affective Outcomes. The few studies examining nocebo effects for affective outcomes suggest they occur (Geers et al., 2021). For instance, participants who encountered negative side-effect information about electromagnetic fields and were then exposed to sham electromagnetic fields (e.g., WiFi signal) were more likely to report more side-effects (e.g.,

perceived pain) *and* higher anxiety, than participants who encountered neutral information before exposure to the sham electromagnetic fields (Bräscher et al., 2017; Verrender et al., 2018). Indeed, Rooney and colleagues' (2024) systematic review and meta-analysis found a medium effect for worsening affect following nocebo manipulation ($g = 0.63$); though this analysis included only five studies. A related narrative review focusing on affect in placebo/nocebo effects similarly concluded that nocebo manipulations—including side-effect warnings—alter people's affective states (e.g., anxiety; Geers et al., 2021).

There is additional incidental evidence for affective-based nocebo effects. Again, I outline some examples but acknowledge that other examples may exist in other literatures. In one example, participants led to believe that clinical psychologists had judged their negative memory for an event to be more negative than other participants' events, showed evidence of nocebo effects after 1 week: participants reported more stress and negative emotions (e.g., sadness) associated with their remembered event, and that their memory was more vivid, compared to participants given no feedback about their negative memory (Takarangi & Strange, 2010). Other evidence comes from the Critical Incident Stress Debriefing (CISD) literature. CISD is an intervention designed for first responders; it involves debriefing and psychoeducation intended to normalise people's reactions to traumatic events (Mitchell & Everly, 1997). Several systematic reviews and meta-analyses have found that outcomes for CISD recipients, compared to a control group, were *similar* (Locher et al., 2019), and in some cases, people reported an increase in PTSD-like symptoms after debriefing (Bisson et al., 1997; Carlier et al., 2000; Hobbs et al., 1996). One explanation for these findings is nocebo effects: perhaps providing people with information about PTSD-like responses made these negative side-effects more likely to occur (Locher et al., 2019; Rose et al., 2003). Together, the available evidence suggests affective nocebo effects occur, and thus, it is possible that risk-warnings could cause nocebo effects for warned of side-effects, like distress.

Other relevant evidence comes from the literature on trigger warnings—that is, research examining alerts that help people prepare and avoid upcoming negative material that might trigger memories/reactions (Bridgland et al., 2022)—that shows how warnings change people's expectancies. Here, researchers have operationalised expectancies as anticipated emotions and pre-existing beliefs (e.g., Bridgland et al., 2019; Sanson et al., 2019). In Gainsburg and Earl's (2018) first study, after exposure to a warning about upcoming content, participants reported anticipated anxiety more than other emotion (e.g., worry). In a subsequent within-subjects study, participants anticipated more negative affect when they viewed video titles accompanied with a warning than without a warning (Gainsburg & Earl, 2018), particularly when they believed trigger warnings were protective than coddling (Gainsburg & Earl, 2018). Furthermore, participants warned that upcoming photographs may be graphic in nature and might cause distress reported more negative affect and anxiety than unwarned participants (Bridgland et al., 2019); other research has found a similar pattern of increased negative expectancy for a trauma analogue film (Sanson et al., 2019). Indeed, in a trigger warning meta-analysis, researchers found a small-to-medium effect (d = 0.43) for reported increases in anticipatory anxiety *after* participants encountered a warning, but *before* they viewed content (Bridgland, Jones, et al., 2023).

Compared to expectancies, there is less support for the idea that trigger warnings cause nocebo-type responding; here, reactions that occur after people have encountered the warned of content. Bridgland, Jones and colleagues' (2023) meta-analysis revealed that trigger warnings did not cause people to react more negatively to warned of, potentially negative, *content* (d = 0.02). However, in one study, participants warned that recalling a negative experience may be *distressing,* and could lead to *negative mood* and *intrusive memories,* experienced a smaller decrease in distress associated with their memory over time (versus unwarned participants; Bridgland & Takarangi, 2021). The authors suggested that

although the negative anticipatory period (i.e., increased anxiety and decreased positive affect) post-warning did not immediately affect warned participants' experience of recalling their event (e.g., distress associated with the memory; Impact of Events Scale) at time one, perhaps this anxiety and decreased positive affect became associated with *recalling* their negative memory, and thus 2 weeks later (i.e., time two), warned participants were more likely to experience a smaller decrease in distress associated with their memory. A second reason this finding may be discrepant from other trigger warning research is that Bridgland and Takarangi's warning contained several person-related side-effects (e.g., you may experience distress, negative mood, intrusive memories), whereas other studies used the term trigger warning with a simple descriptor (e.g., "Trigger warning: sexual abuse"; e.g., Bruce & Roberts, 2020; Sanson et al., 2019) or warnings that suggested the upcoming *content* or *material* might be disturbing or distressing, instead of the person being distressed (e.g., Bridgland & Takarangi, 2021; Gainsburg & Earl, 2018).

Despite trigger warning research providing insights into whether risk-warnings change people's expectancies and cause nocebo effects, there are limitations to generalising these findings to our context. Notably, trigger warnings are not part of the consent process itself. For instance, in trigger warning paradigms, participants usually complete consent procedures for the study itself, *then* view their respective warnings, and respond to psychological measures (e.g., anxiety). Further, in some studies, expectancies relate to the study/content itself (e.g., how negative the upcoming film will be; e.g., Sanson et al., 2019), rather than person-related side-effects (e.g., how distressed someone thinks they will be) or reflecting on participation in trauma-related research as a whole.

Prior Informed Consent Risk-Warning Research

Now I will consider evidence for studies investigating nocebo effects in informed consent contexts specifically. Few empirical studies have examined how warnings provided

during the consent process—instead of within the study itself—affect participant reactions. Most of this work focuses on medical-based—rather than psychological—outcomes.

Informed Consent and Nocebo Effects for Medical-Based Outcomes

Several published works converge on the idea that the informed consent process contributes to nocebo effects for medical-based outcomes, most likely through side-effects suggested via risk information (e.g., side-effect warnings; e.g., Colloca, 2024, Colloca & Miller, 2011; Faasse & Petrie, 2013; Myers et al., 1987). One line of evidence comes from placebo-controlled clinical trials, where some participants receiving placebo treatment report adverse outcomes in line with risk information communicated during consent procedures (Barsky et al., 2002; Colloca, 2024). For instance, placebo participants in a migraine drug trial reported outcomes consistent with side-effects the researcher outlined, such as memory difficulties (see Amanzio et al.'s 2009 systematic review). There is a similar pattern of findings for drug trials investigating antidepressants (e.g., Mitsikostas et al., 2014; Rief et al., 2009) and headaches (e.g., Mitsikostas et al., 2011; Reuter et al., 2003).

A second line of evidence comes from research that provides people with different risk information at consent. In Myers and colleagues' (1987) hallmark study, participants involved in a drug trial to treat angina (i.e., heart condition) at two separate hospitals received different consent risk information—reflecting different IRB requirements. Participants informed about minor gastrointestinal (GI) side-effects—compared to participants who were uninformed—reported more GI side-effects and were more likely to withdraw from treatment because of the GI side-effects. However, in drawing conclusions from these findings, it is important to note that Myers et al. relied on a convenience sample, so participants were not randomly allocated, and results were potentially confounded by location (Myers et al., 1987).

Recent experimental work overcomes these methodological limitations with mixed findings. Empirical evidence in favour of nocebo effects shows participants warned their

appetite may change (i.e., increase or decrease) after they consumed a placebo pill (versus no pill) reported changed appetite (Neukirch & Colagiuri, 2015). But other work reports null findings (e.g., Holzhüter & Hamann, 2020; Wilhelm et al., 2018), including for negative expectations (e.g., Heisig et al., 2015). For instance, there was no statistical difference on side-effect impairment measures between in-patients provided with a known, inactive pill (i.e., open-label procedure) and either consent side-effect or no side-effect information (Holzhüter & Hamann, 2020).

In summary, several lines of evidence from the medical nocebo literature suggest the informed consent process changes people's expectancies and subsequently causes nocebo effects. Therefore, it is possible that this nocebo effect-type chain that occurs in medical contexts may also occur for consent risk-warnings in a psychological trauma-related context.

Informed Consent and Nocebo Effects for Psychological-Based Outcomes

Of two known experiments investigating risk-warnings delivered as part of informed consent on psychological-based outcomes, results diverge. de Wied and colleagues (1997) found that participants exposed to a violent warning (i.e., upcoming film contained violent material) reported more distress post-film than participants exposed to an edited warning (i.e., that the upcoming film had the violent material edited from the film). Conversely, Senn and Desmarais (2006) randomly allocated participants to view a consent form containing either procedure-only information (e.g., description of the questionnaires asking about personal experiences), procedure and minimal content information (e.g., "The slides may contain sexually explicit and/or violent content…"), or procedure and detailed content information highlighting stressful elements of the procedure (e.g., "…the images may be upsetting or objectionable to some people…"), before viewing sexually explicit content. In the first experiment, participants who received minimal or detailed content evaluated the sexually explicit content as more negative than the procedure-only condition. However, when

participants encountered similar warnings about answering questions (e.g., about sexual activity; Experiment 2), the results pattern did not replicate. Senn and Desmarais also measured participants' *expectations*, finding that people who encountered a stressful/personal-focused warning were more likely to report that study questions did not match their expectations. Thus, these findings suggest risk-warnings, under some experimental circumstances, alter how participants react to content within research studies.

The Psychological Underpinnings of Nocebo Effects

Several psychological-based theories explain how suggestions about side-effects, delivered via risk-warnings, might cause nocebo effects for psychological outcomes, such as distress.

Priming

One overarching mechanism that applies to our risk-warning nocebo effect possibility is *priming* (e.g., Janiszewski & Wyer, 2014). Though definitions vary between sub-disciplines (e.g., social and cognitive psychology), broadly speaking priming involves providing people with a stimulus (e.g., a side-effect warning) that increases the availability or accessibility of underlying mental concepts (e.g., memories about past side-effect reactions, affect), and influences responding (e.g., responding faster to negatively valenced words; e.g., Janiszewski & Wyer, 2014; Minton et al., 2017). As some basic examples of cognitive priming, participants first primed with mortality-related words (e.g., died, coffin) responded faster to death-related words (e.g., deadly) on a subsequent lexical decision task (i.e., *semantic priming;* Huang & Wyer, 2015). Similarly, participants exposed to a negative news article recalled more negative information from subsequent news articles, relative to participants exposed to a positive news article (*affective priming;* Baumgartner & Wirth, 2012). Indeed, semantic and affective priming show how risk-warnings might negatively

prime people—via semantic and affective channels—influencing people's interpretation of their reactions during trauma-related research participation.

Priming has been extended from its roots in experimental word priming tasks to consumer research settings (Janiszewski & Wyer, 2014; Minton et al., 2017). Consumer behaviour researchers have conceptualised priming theories into prospective and retrospective accounts (Minton et al., 2017). Prospective priming theories suggest priming predominantly occurs *after* a person has encountered the prime (e.g., consent risk-warning), but before they encounter a target (e.g., participation experience; Minton et al., 2017). Conversely, retrospective theories propose that priming begins after a person has encountered both the prime and the target (Minton et al., 2016). Both *prospective* and *retrospective* priming theories help explain how risk-warnings could cause psychological nocebo effects (Minton et al., 2017).

Prospective Priming Theories. According to this approach, risk-warnings for side-effects (e.g., distress) may first increase the availability of distress-related concepts (e.g., anxiety, fear, upset) and lead people to interpret their research experience in this way (i.e., as being anxiety-provoking). Specifically, spreading activation theory suggests that when a concept (e.g., red) is primed, related constructs (e.g., roses, flowers) are rapidly activated in memory, making them easily accessible (Collins & Loftus, 1975; Quillian, 1967). Consequently, if a person was asked to recall a flower, they would be more likely to recall "rose". In the warning context, risk-warnings in trauma-related research might prime negative psychological concepts that activate associated negative concepts (e.g., anxiety, trauma symptoms). Alternatively, expectancy theory proposes that when a person encounters a prime (e.g., risk-warning including negative side-effects), they develop "a set of expected targets" (e.g., feeling negative side-effects because of participation; Minton et al., 2017).

Hence, when exposed to the expected targets, this feeling process is more likely to occur faster than if they had not encountered the prime.

Retrospective Priming Theories. According to this approach, participants encounter the risk-warning (e.g., "you may feel distressed") *and* participate in trauma-related research, before priming occurs. Semantic matching theory, for instance, suggests people use the prime and target together to make meaning of the target (Minton et al., 2017). Though this theory originated in lexical-based tasks (e.g., words pairs: dog-cat), it still suggests how people exposed to a risk-warning and participation may use the prime—after their participation—to make sense of their trauma-related participation experience. For example, after participation, a person may use the risk-warning information to judge their participation experience as being more negative than if they had not been primed. Another possibility, compound cue theory, proposes that the prime (i.e., risk-warning) and target (i.e., participation) are combined to form a compound cue (McKoon & Ratcliff, 1989; Minton et al., 2017). Together, this cue is matched to other compounds—relating to risk-warning information and participation experiences—stored in long-term memory (McKoon & Ratcliff; 1989; Minton et al., 2017). Consequently, this stronger memory trace increases activation of underlying concepts and might influence how people respond when asked to recall their participation experience (e.g., recalling the experience as being more negative than it was), by retrospectively priming them.

It is also possible for prospective and retrospective priming theories to work together via Neely and Keefe's (1989) three-stage model. In a risk-warning context, this three-stage model may look like: a person encounters the risk-warning (e.g., "you may experience distress"), which makes related concepts in memory (e.g., past experiences that made them feel distress) more accessible (i.e., spreading activation); using these accessible constructs, the person develops a set of expected targets (e.g., "I expect participation to cause distress";

i.e., expectancy); and finally, after participation, they use the warning to make sense of their experience (e.g., as being more negative according to warned of side-effects; Minton et al., 2017; Neeley & Keefe, 1989). Together, priming and its associated sub-theories outline several avenues for how consent risk-warnings might cause psychological nocebo effects.

Response Expectancy. One form of prospective priming, and specific expectancy theory, *response expectancy*, proposes that people anticipate their own automatic, subjective behavioural reactions to situational cues (Kirsch, 1985; 1997). For instance, expecting to become more sociable after consuming alcohol or alert after consuming caffeine will lead to these outcomes (Kirsch, 1985; 1997). Indeed, in psychological intervention research, phobic anxiety severity (i.e., anxiety disorder involving phobias) was associated with anxiety expectancies (e.g., Kirsch et al., 1983; 2016; Southwork & Kirsch, 1988). Moreover, how much people believed they would improve post-treatment was also associated with actual improvement (e.g., Kirsch et al., 1983; 2016; Southwork & Kirsch, 1988). Response expectancies are therefore about people's own experiences—including their internal experiences—and behaviours, rather than about someone else's (Kirsch & Lynn, 1999; Kirsch, 2016).

Given expectancies are one prominent mechanism for nocebo effects (e.g., Benedetti et al., 2007; Montgomery & Kirsch, 1997; Rooney et al., 2023), and they align with priming, my thesis will focus on response expectancies to understand how risk-warnings may cause psychological nocebo effects for participants. Here, I operationalise response expectancies within a nocebo effect type chain reaction, whereby side-effects *suggested* via consent risk-warnings change participants' expectancies, and subsequently cause negative psychological outcomes (i.e., nocebo effects; e.g., Rooney et al., 2023). Indeed, we know from previous research that some people are highly susceptible to suggestion (e.g., Lifshitz et al., 2013; Loftus, 2017; 2005; Michael et al., 2012).

Bayesian Theory. One theoretical account that shares a "close affinity" with expectancy theory is *Bayesian theory* (Kirsch, 2018, pp. 83-84; Ongaro & Kaptchuk, 2019). According to this theory, we perceive our world according to probability. People have a default understanding of the world (i.e., prior), and when people encounter new evidence (e.g., internal sensations, external information), they need to weigh this evidence against their existing understanding, potentially updating their prior if necessary (Ongaro & Kaptchuk, 2019). In a health context, for instance, a person's prior might be that they have a healthy body (Ongaro & Kaptchuk, 2019). This existing understanding allows for some deviation (e.g., body aches) without the person changing their prior. When new evidence is presented that represents a large enough deviation—a cough, for instance—the person must update their prior (e.g., that they are sick; Ongaro & Kaptchuk, 2019). Thus, Bayesian theory explains how physical symptoms—or interpretation of them—can be reported in the absence of a physical cause.

However, Bayesian theory may also account for psychological outcomes. Indeed, Bayesian perspectives, including "Bayes rule" and "Bayesian updating of beliefs", have been applied to psychological research (e.g., Achtziger & Alós-Ferrer, 2014; Coutts, 2019). In a risk-warning context, a person's prior when first entering into a study context might be that they are currently feeling neutral/calm). However, information about psychological side-effects (i.e., new evidence) may cause a person to question their default prior (i.e., "this information suggests I should be feeling nervous/anxious") and subsequently heighten their sensitivity to negative feelings, such as anticipatory anxiety that may occur when beginning a new task (see Labuschagne et al., 2019 for similar acclimation period discussion). This heightening may mean participants attend to negative feelings and update their prior in line with the new evidence encountered (e.g., "I am not calm"). Thus, complementary to response

expectancy theory, I will also consider Bayesian theory when exploring whether consent risk-warnings cause psychological nocebo effects.

Informed Consent Risk-Warnings in Trauma-Related Research

To my knowledge, only one experiment examines nocebo effects within the context of *trauma*-related informed consent risk-warnings. In Bussell's (2017) doctoral thesis, participants were randomly allocated to view one of two consent forms: one that used harsher language (i.e., "…some people are emotionally distressed…") and concentrated on risks associated with participation; and one that contained balanced benefit and risk information, where risks were described using trauma-informed language (e.g., "The risks associated with participating are no worse than those you would encounter in everyday life…"). Participants then completed psychopathological measures (e.g., PTSD Checklist for DSM-5) either via interview or self-report. Overall, there was no effect of consent form language type on psychopathology measures; that is, there was limited evidence to suggest nocebo effects occurred. However, the effect of consent form language type depended on whether participants provided responses via self-report or interview. Participants who encountered the harsh language consent forms *self-reported* more depressive symptoms and PTSD-like symptomology, perhaps due to demand, or because the harsher language helped people feel more comfortable in reporting their true symptoms. While Bussell speculated about these possibilities, due to their study design, they were unable to disentangle such possibilities. Potentially, the interview context provided participants with therapeutic benefit via social support and erased any effects associated with the different risk descriptions. Therefore, this study suggests that it might not be the risk-warning driving nocebo effects, but rather the interaction between risk-warning and participation mode (i.e., interview or self-report).

There are however drawbacks to these informed consent risk-warning studies. First, these studies lacked a true control condition (i.e., where participants received no warning).

Although it is ethically challenging to incorporate a control condition into study design, without one we cannot determine whether nocebo effects are present. For example, prior research indicates that if participants encounter a warning, they respond differently to people who do not encounter a warning (e.g., Bridgland et al., 2019; Faasse, Huynh et al., 2019). Second, only one study measured participant expectancies, and this measurement was specific to the study's purpose (i.e., content), instead of to personal reactions (e.g., distress, anxiety). Finally, only one study addressed consent risk-warnings in a psychological trauma-related research context. Therefore, not only is it unclear what effect risk-warnings have on participants (i.e., regarding experienced side-effects), it remains possible that these risk-warnings cause psychological nocebo effects.

Overview of Consent Risk-Warning Work

Taken together, the final part of my thesis examines whether informed consent risk-warnings—that warn of potential psychological side-effects in trauma-related research—cause psychological nocebo effects for participants. To first understand how previous empirical work has investigated whether risk-warnings, delivered at the time of consent, change people's expectancies and cause nocebo effects, I conduct a scoping review in Chapter 7. This chapter finds that not only is empirical work scant across medical and psychological-based outcomes, but of the existing research, there are several methodological limitations (e.g., indirect measurement, small sample size, lack of appropriate control condition). Thus, Chapter 7 summarises the available literature and provides recommendations for future experimental work on risk-warning research.

In the following chapters, I test the nocebo effect-type chain by experimentally manipulating risk-warnings at the point of consent to determine if they change participant expectancies (Chapter 8) and cause psychological nocebo effects (Chapter 9). Across three experiments, the nocebo effect-type chain is not realised. Specifically, in Chapter 8, different

risk-warnings, including comparisons to a no warning condition, did not cause participants to expect to experience warned of side-effects (e.g., distress). In fact, my findings suggest that participants disagreed that they expected to experience warned of side-effects. In Chapter 9, providing a consent risk-warning for an analogue trauma study did not lead participants to expect the warned of side-effects (e.g., distress), nor to experience nocebo effects, relative to a no warning (i.e., no side-effects) condition.

Chapter 7: Nocebo effects on informed consent within medical and psychological settings: A scoping review[32]

Author contributions: I conceptualised the scoping review and developed the scoping review criteria. I screened papers, alongside an independent coder and VMEB. I interpreted the papers and drafted the manuscript. MKTT and VME provided critical revisions and approved the final version of the manuscript for submission.

Abstract

Warning research participants and patients about potential risks associated with participation/treatment is a fundamental part of consent (NHMRC, 2018). However, such risk-warnings might cause negative expectations and subsequent nocebo effects (i.e., negative expectations *cause* negative outcomes) in participants (e.g., Loftus & Fries, 2008). Because no existing review documents how past research has *quantitatively* examined nocebo effects—and negative expectations—arising from consent risk-warnings, we conducted a pre-registered scoping review ($N = 9$). We identified several methodological issues across these studies, which in addition to mixed findings, limits conclusions about whether risk-warnings cause nocebo effects.

Introduction

"After all, we don't want the return of the bad old days when unwitting human guinea pigs were experimented upon without knowing what they were getting into" (Loftus & Fries, 2008, p. 217). Indeed, informed consent practices are a cornerstone in contemporary ethics guidelines, forming one of the predominant ways that researchers and health care practitioners convey *respect* for people (e.g., NHMRC, 2018). Consent practices help people to make *informed* decisions about participation and treatment, thus respecting *autonomy*

[32] Stirling, N. S. J., Bridgland, V. M. E., & Takarangi, M. K. T. (2023). Nocebo effects on informed consent within medical and psychological settings: A scoping review, *Ethics & Behavior, 33*(5), 387-412.

(Gelfand, 2020). Despite the well-intentioned nature of such practices, several researchers have raised the worrying possibility that warning participants and patients about potentially adverse outcomes—e.g., risks and/or side-effects—may inadvertently cause such adverse outcomes to occur (e.g., Cohen, 2014; Colloca, 2017; Loftus & Fries, 2008; Michael et al., 2012; Wells & Kaptchuk, 2012; Zech et al., 2015). In other words, these warnings may lead to a *nocebo effect*—when negative expectancies *cause* negative outcomes (Barsky et al., 2002; Hahn, 1997). However, extant literature on informed consent and nocebo effects typically focuses on theoretical ideas (i.e., what nocebo effects may mean for participant/patient rights; e.g., Cohen, 2014; Loftus & Fries, 2008; Loftus & Fries, 1979; Wells & Kaptchuk, 2012) or on offering potential solutions to nocebo effects that may arise at the time of consent (e.g., Barnes et al., 2019; Colloca, 2015). We know of no review that integrates *empirical* investigations of nocebo effects that may arise because of consent risk-warnings (i.e., delivered at the time of consent). Knowing this evidence base for the potential problem is an important first step before pursuing solutions (e.g., Crichton & Petrie, 2015). Thus, here we aim to document how prior research has *quantitatively* examined risks communicated *at the time of consent*—that is, the time at which people choose to consent or not consent after learning of information associated with a procedure, drug, or participation—and nocebo effects, and outline where current understanding of this phenomena stands.

The possibility of nocebo effects resulting from consent form risk-warnings is an important ethical issue facing researchers and health care practitioners alike. On the one hand, it is morally imperative—and ethically required (e.g., NHMRC, 2018)—to provide people with information about an upcoming experience (i.e., "informed" consent)—be it a medical procedure, drug administration, or participation in research. That information must be sufficient for people to decide whether to opt in to this experience, given their own values, life experiences, and desires (i.e., people's sense of autonomy; NHMRC, 2018). Here, the

goal is to respect people's right to make decisions that are within their best interests. Yet, on the other hand, providing sufficient information—specifically, communicating potential risks associated with treatment or participation—may inadvertently bring about the experience of such risks; termed nocebo effects (Barsky et al., 2002; Hahn, 1997). Ethically speaking, if patients and/or participants experience nocebo effects because of risk-warnings communicated during consent, both practitioners and researchers may be violating the ethical principle of beneficence (i.e., acting in good faith); or non-maleficence (i.e., to avoid harm; see Cohen, 2014 or Colloca, 2017 for a detailed ethical discussion specific to clinical settings; NHMRC, 2018). Put differently, researchers and health care practitioners could be inadvertently causing people harm via consent practices (i.e., risk-warnings). And therein lies the ethical conundrum; striking an appropriate balance between the ethical principles of autonomy and beneficence. But, prior to engaging with this debate, it is important to first gather quantitative evidence to examine whether consent form risk-warnings do cause negative expectancies and subsequent nocebo effects.

Although there is a small literature on nocebo effects generally, such effects have been reported across several domains. Within the medical-related domain, there have been multiple reports of participants in the placebo arm of randomised placebo-controlled drug trials reporting adverse outcomes that are consistent with warned about side-effects of the *active* medication (e.g., Reuter et al., 2003). For example, participants given a placebo pill (i.e., inert substance) reported memory difficulties consistent with side-effects they were warned about for an *active* anti-migraine drug (Amanzio et al., 2009). In another example, 43.65% of patients prescribed an active medication (i.e., finasteride) for prostate enlargement who were warned about potential sexual-related effects (e.g., erectile dysfunction) reported such adverse sex-related effects, relative to only 15.3% of patients not warned (Mondaini et al., 2007). Further, recent reviews within the medical domain on pain and itch—including a

meta-analysis and systematic review—show clear evidence for nocebo effects (e.g., moderate-to-large effect sizes for nocebo effects associated with pain; Bartels et al., 2016; Meeuwis et al., 2020; Petersen et al., 2014). There is also evidence of nocebo effects, though to a lesser extent, for psychological outcomes (e.g., Michael et al., 2012). For example, within the memory domain, participants told that their negative memory for an event was *more negative,* relative to other participants who were given no feedback, reported more stress, negative emotions (e.g., sadness) and that their memory was more vivid, after 1 week (Takarangi & Strange, 2010). Prior research examining trigger warnings (i.e., warnings provided prior to people viewing sensitive content related to traumatic experiences; Bridgland et al., 2022) found that participants who were warned the photographs they were about to view were graphic in nature—and may cause distress—reported higher negative affect and state anxiety versus unwarned participants (Bridgland et al., 2019). Further, participants warned that recalling a negative personal experience may lead to distress, negative mood, and intrusive memories, reported increased anxiety post-warning, relative to unwarned participants (Bridgland & Takarangi, 2021). Together, these studies across medical and psychological domains highlight the pervasiveness of nocebo effects.

Though debate ensues (e.g., Rief et al., 2008), one possible explanation for nocebo effects is expectancy (Montgomery & Kirsch, 1997; see Planès et al., 2016 for exploration of other factors that may explain nocebo effects, such as conditioning). Expectancy theory suggests that expectancies about an outcome—either positive or negative—can ultimately shape that outcome in line with the expectancy (Kirsch, 1997). For example, warning people that an upcoming experience might be distressing may lead them to form a negative expectation that the experience will be distressing. Such an expectation may in turn result in the person paying closer attention to the negative and/or potentially distressing aspects of participation, therefore magnifying the level of distress they experience. Regarding nocebo

effects, the idea is therefore that people who form a negative expectation—either internally (e.g., self-generated via a lucky charm) or externally (e.g., deliberate or unintentional suggestion via a researcher's suggestion; Michael et al., 2012)—may go on to enact the outcome of their negative expectation (e.g., feeling more distressed; Kirsch, 1985; 1997). In one example, participants undergoing a procedure to reduce Parkinson's disease symptoms were either told that their motor performance would worsen (i.e., negative expectation) or that it would improve slightly (i.e., positive expectation; Pollo et al., 2002). Although the procedure was designed to help patients, only participants who were told their motor performance would improve showed improvements; those told the treatment would worsen displayed decreased performance. Thus, it is also important to consider *negative expectancies* within the context of consent.

Of course, the research community recognises the importance of nocebo effects—and negative expectancies—resulting from consent practices (e.g., Colloca, 2017). Past reviews have gathered evidence on strategies for reducing the nocebo effect in medical settings (e.g., Barnes et al., 2019; Planès et al., 2016), discussed evidence for mechanisms of the nocebo effect (e.g., Faasse, 2019), or the implications for nocebo effects resulting from consent on ethical practice (e.g., Cohen, 2014). But, to our knowledge, no review integrates how past research has quantitatively examined nocebo effects *at the time of consent* (i.e., when people are required to use provided information to either consent or not consent to research participation, drug administration, or a procedure), including where understanding currently stands. Therefore, to address this limitation, we will examine via scoping review how extant literature in medical and psychological-based settings has quantitatively examined nocebo effects within an informed consent context.

Inclusion Criteria

Participants

We included participants of any gender, race, or ethnicity. However, we only included participants aged 18 years or older (i.e., not minor) because people aged 18 and below may be unable to provide consent, which may complicate the relationship (i.e., between consent risk-warnings and nocebo effects) we are interested in (e.g., their parents may consent on their behalf or influence their decision to consent).

Concept

We had two phenomena of interest. First, *nocebo effects*; defined as adverse effects associated with negative expectancies about an outcome (Barsky et al., 2002; Hahn, 1997). Second, and relatedly, *negative expectancies*; defined as negative expectations created via suggestion or framing that helps shape the outcome in line with said expectancy (Michael et al., 2012; Montgomery & Kirsch, 1997).

Because our interest in these phenomena was within the context of informed consent, we only considered negative expectancies and nocebo effects that occurred at the time of consent, meaning when people were required to either consent or not consent to drug administration, research participation, or a procedure. So long as the consent information—specifically risk information—was delivered on one occasion, it was included in the review (e.g., delivery via consent form, leaflet, verbal explanation by experimenter).

For the purposes of our review, we only considered consent information delivered on one occasion—where people had to either consent or not consent—for two reasons. First, because our review was concerned with gathering quantitative evidence on whether nocebo effects occur because of risk-warnings presented at consent, we wished to minimise possible extraneous variables or double-effects. For example, if participants received a warning at the time of consent, but also another warning prior to the actual participation experience (e.g.,

answering questions about a past traumatic experience), procedure, or drug administration, we would be unable to tease apart the influence of multiple warnings from any warning at all, from the way the risk was presented in the warning, or from no warning. Second, if people have already provided consent—that is, they have already weighed up whether the research participation, procedure, or drug administration, is a suitable choice for them—they may engage in a different type of risk appraisal when they are subsequently warned or instructed. Indeed, prior research using an American sample indicates over half of people (62%) who viewed and signed a consent form to participate in a psychological research study—compared to people who viewed an information leaflet about the study that did not require participants' signature—believed they could no longer sue researchers for negligence (i.e., participants believed they had forfeited their rights; Mann, 1994). Therefore, administering additional consent-related procedures—such as verbally framing pain associated with a needle, "You will feel a big prick" versus "You will feel comfortable" (e.g., Varelmann et al., 2010)—after consent to the procedure has initially occurred may influence people's responses. Subsequently, this study design may not offer an opportunity to clearly examine—and draw causal conclusions about—the phenomenon we were interested in here.

Context

Our review included negative expectancies and nocebo effects that occurred at consent within medical (e.g., pain) and psychological-based settings (e.g., cognitive functions).

Types of Studies

We considered experimental and quasi-experimental designs, as well as analytical observational studies (e.g., observational studies that included statistical analyses). Because the purpose here was to document past *quantitative* research, we did not include descriptive observational study designs (e.g., case studies that include a rating scale for a small number

of people); such designs would limit the strength of casual statements made in this review. We otherwise took a broad approach toward the number of participants, settings (i.e., all medical- and psychological-based), and outcome measures used in the studies.

Methods

We conducted this scoping review in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews (Tufanaru et al., 2017). We pre-registered our scoping review on the Open Science Framework (OSF) using the JBI scoping review protocol template (https://osf.io/6ekdr/).

Search Strategy

We aimed to include published and unpublished studies, and used a three-step approach to identify relevant studies. First, we conducted a limited search of PsycINFO and MEDLINE on 15th June 2021 to identify relevant articles on the topic. We examined text words contained in the titles and abstracts of relevant articles, in addition to subject headings, to find key words/terms. Second, we used the identified key words/terms to develop our full search strategy (see Supplementary Files at the end of this Chapter) and piloted our search; this process included adapting each search to the relevant database(s). Finally, we screened the reference list(s) of included sources for additional studies.

We included studies published in English—due to resource constraints—and of all dates. We searched for sources on 9th August 2021. For published works, we searched: PsycINFO, MEDLINE, PubMed, ProQuest, and Web of Science. For unpublished works, we searched ProQuest Dissertations and Theses Global.

Study Selection

We uploaded our search results into EndNote 20[33] and removed duplicates. Next, we uploaded search results to the JBI System for the Unified Management, Assessment, and Review of Information (JBI SUMARI; Peters et al., 2021). The titles and abstracts of all sources were reviewed by three independent reviewers (SC, CS, NS) in line with the inclusion criteria. Each source that fit our inclusion criteria was reviewed in full by three independent reviewers (SC, VB, NS); reviewers also examined reference lists for additional sources that met criteria for this review. Such sources were added to full-text screening and their inclusion was agreed by all three reviewers. All conflicts that arose during the screening process—both title and abstract and full-text screening—were resolved via discussion between the three reviewers.

Data Extraction

Data were independently extracted from included sources by two independent reviewers (VB, NS) using the standardised data extraction tool in JBI SUMARI (e.g., country, context, participant characteristics, conditions, outcomes measured, description of main results; Aromataris & Munn, 2020). We also included study design and limitations of study.

Data Analysis and Presentation

We present the data below in a tabular format that aligns with the aims of this scoping review. To help address our first aim (i.e., to present articles that quantitatively examine nocebo effects and expectancy effects on informed consent), we group similar study types together to provide further description of key information in the tabular format (e.g., study design, main results, limitations). Further, we provide a narrative summary of what the

[33] *Note.* Due to resource constraints, we deviated from our registered protocol and used EndNote 20 rather than EndNote X9.

quantitative literature informs us about the relationship between nocebo effects and expectancy effects on informed consent, in addition to limitations—both global and at the individual study level—of this area of research.

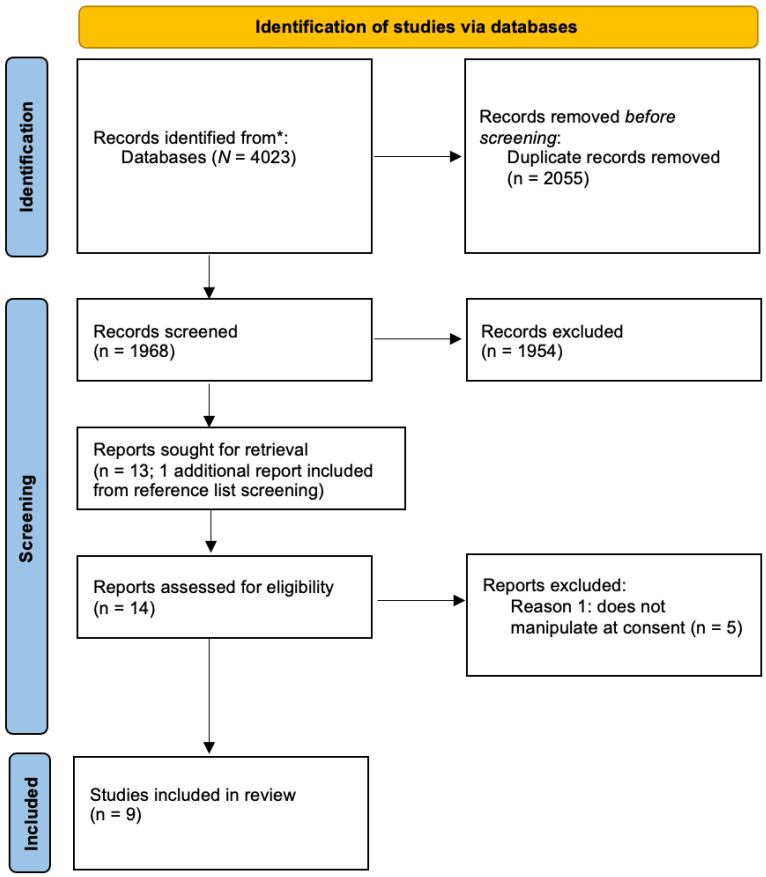
Results

Study Inclusion

Our search of six databases identified 4,023 sources. After removing duplicates, we reviewed 1968 titles and abstracts for eligibility; 13 proceeded to full-text screening. We identified one article that met inclusion criteria for this review via screening of included papers' reference lists. We excluded five articles because they did not meet inclusion criteria. Our final sample consisted of nine articles. The Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews (PRISMA-ScR; Tricco et al., 2018) flowchart shows our article selection process (see Figure 7.1).

Figure 7.1

Identification, Screening, and Inclusion Process for Scoping Review



Characteristics of Included Studies

The included studies were two unpublished doctoral theses and seven peer-reviewed empirical articles, all of which examined nocebo effects and/or expectancy effects at the time of informed consent. Of these nine articles, four were based in a psychological outcome context and the remainder in a medical outcome context. The articles have a Western focus, having mostly occurred in Germany (3) and the United States of America (3), Canada (2), and Australia (1). Almost all studies used a between-subjects, randomised design, except for Myers and colleagues (1987), which used a self-selected sample (i.e., quasi-experimental design) dependent on hospital location.

Review Findings

A summary of our findings appears in Table 7.1.

Medical Outcome Settings

Of the five studies that occurred in a medical outcome context, two focused on side-effects to active medication (Myers et al., 1987; Wilhelm et al., 2018), one on side-effects to a sham medication for sleep difficulties (i.e., pill was actually a placebo pill; Neukirch & Colagiuri, 2015), one on side-effects to open-label placebo treatments (i.e., participants are told they will receive a placebo pill; Holzhüter & Hamann, 2020), and one on side-effect expectations to an imagined cancer scenario (Heisig et al., 2015).

Sample characteristics differed considerably between the studies, ranging in size (i.e., 51-555 participants), with the mean reported age varying from 21.3 to 51.6 years. Two studies included only one gender (male only; Wilhelm et al., 2018, female only; Heisig et al., 2015), one study included both genders with a skew toward females (Neukirch & Colagiuri, 2015), while other studies included a mixture of genders but did not report the sample breakdown (Holzhüter & Hamann, 2020; Myers et al., 1987). Two studies relied on psychiatric (diagnosed depression) and medical (diagnosed unstable angina) clinical samples (Holzhüter & Hamann, 2020; Myers et al., 1987), one on a community sample (Heisig et al., 2015), and another on an undergraduate sample (Neukirch & Colagiuri, 2015); Wilhelm and colleagues presumably used an undergraduate sample, but it is unclear based on the manuscript.

Table 7.1

Tabular Summary of Data Extraction Variables

Source	Country and Context	Study Design	Sample Size and Participant Characteristics	Conditions	Outcomes Measured	Main Results	Limitations
Medical Outcome Context							
Wilhelm, Rief, and Doering (2018)	Conducted in Germany. Medical/physical outcome context: medication side-effects.	Randomised, 2 (framing condition: positive, neutral) between-subjects. Double-blind.	*N* = 80. Only male participants aged 18-30 years old.*	All participants received a betablocker. Consent information was manipulated between-subjects: Condition 1: participants (*n* = 40) received positively framed consent information ("If you become dizzy after taking the medication, it means your body is responding to the betablocker particularly well.") Condition 2: participants (*n* = 40) received neutral framed consent information ("This is a potentially unpleasant, but already known side-effect of the drug.")	Reported side-effects (Generic Assessment of Side-Effects Scale). Beliefs about medicine (Beliefs About Medicines Questionnaire). Physiological data (heart rate).	Participants that received the neutral framing condition experienced more dizziness than participants in the positive framing condition (one-tailed test). Participants in the positive framing condition perceived drug attributed symptoms as less threatening (side-effects questionnaire).	Only included healthy males. May not have created expectations because they were not sick to begin with.
Holzhüter and Hamann (2020)	Conducted in Germany. Medical/physical outcome context: placebo medication side-effects.	Randomised 2 (intervention type: intervention, control) between-subjects. Subjective-blind. Open-label procedure.	*N* = 51. Both males and females (but % not included), aged 18-80 years old.* Inclusion criteria: diagnosed depressive and sleep disorder, had to be on medication.	All participants received an open-label placebo pill (i.e., participants knew the pill was a placebo pill). Consent information was manipulated between-subjects: Condition 1: participants (*n* = 26) received detailed	Subjective evaluation of sleep (e.g., "How well did you sleep last night?"). Experience with and reported side-effects of the placebo pill (e.g., "How satisfied	No significant differences between conditions on any outcomes measured.	Small sample size, thus, analyses were likely underpowered. Open-label procedure, therefore, may have reduced

				information about the placebo 'sleeping' pill's effectiveness, as well as non-specific side-effects (e.g., dry mouth, vertigo, sweating). This information was presented using framing (e.g., "Around 30% of all patients report dry mouth). Condition 2: participants (n = 25) were not given any information regarding the pill's effectiveness or side-effects. The consent form was otherwise identical to Condition 1.	have you been with the new drug?", "How much did the new drug cause side-effects?").		believability of manipulation.
Heisig, Shedden-Mora, and Nestoriuc (2015; Study 1)	Conducted in Germany. Medical/physical outcome context: side-effects of imagined cancer treatment.	Randomised 2 (framing: emphasises benefits, does not emphasise benefits) x 2 (presentation: personalised talk, standardised business-like interaction), between-subjects, pre- and post-design.	N = 60. Only female participants aged 28-79 (M = 51.6, SD = 12.4).	All participants completed a future-thinking task. Consent information was manipulated between-subjects: Condition 1: participants received information that emphasised the benefits of the cancer treatment. Participants were further split into two conditions: emphasised benefits via a personalised talk (n = 15), emphasised benefits via a standardised business-like interaction (n = 16). Condition 2: participants received information that did not emphasise the benefits of the cancer treatment. Participants were further split into two conditions: no emphasised benefits via a personalised	Trait anxiety (STAI). Informational coping styles and monitoring and blunting (Threatening Medical Situations Inventory). Intention to start treatment (e.g., "How certain are you to start endocrine therapy?). Necessity concern balance (Beliefs About Medication Questionnaire). Expected side-effects (General Assessment of Side-Effects Scale).	Participants in Condition 1 reported lower side-effect expectations and lower decisional conflicts than participants in Condition 2.	Used a future-thinking scenario, therefore there may have been an intention-behaviour gap. The sample consisted of healthy participants and therefore, imagining making a decision about cancer treatment may have been difficult.

				talk (n = 15), no emphasised benefits via a standardised business-like interaction (n = 14).	Decisional conflicts (Decisional Conflicts Scale).		
Heisig, Shedden-Mora, and Nestoriuc (2015; Study 2)	As above.	As above.	N = 64. Female participants aged 31-71 (M_{age} = 49.6, SD = 11.1).	As above. Note however, all conditions had n = 16 participants.	As above.	Participants in Condition 1 reported a more functional necessity concern balance than Condition 2.	As above.
Myers, Cairns, and Singer (1987)	Conducted in Canada. Medical outcome context: side-effects of medication on unstable angina.	Randomised to medication administration conditions. However, consent information part of quasi-experimental design because participants self-selected based on location of hospital. Longitudinal study (occurred over 2 years).	N = 555. Patients that were admitted to hospital with unstable angina pectoris.	Conditions 1 and 2: participants received consent information that included side-effect warnings regarding gastrointestinal (GI) irritation and skin rash. Condition 3: participants received consent information, however, the information did not mention specific side-effects as above, but instead, listed bleeding and haemorrhage as side-effects.	Reported symptoms/side-effects. Physical examination and ECG.	Minor GI symptoms were reported less frequently in Condition 3 in comparison to Conditions 1 and 2. More patients in Conditions 1 and 2 discontinued treatment as a result of GI symptoms than participants in Condition 3.	The main manipulation (i.e., side-effects) was confounded by location (i.e., conditions were located at different hospitals). No random allocation.
Neukirch and Colagiuri (2015)	Conducted in Australia. Medical outcome context: side-effects of placebo treatment.	Randomised 2 (side-effect warning: warning, no warning) x 2 (treatment: placebo, no placebo), between-subjects design.	N = 91. Both males and females, with 61% of the sample female and M_{age} = 21.3. Undergraduate students with self-identified sleep difficulty of at least 3 nights per week.	Condition 1: participants received consent information that warned the medication may cause an increase or decrease (counterbalanced between conditions) in appetite. Participants were further split into: warning with placebo treatment and warning without placebo treatment. Condition 2: participants received consent	Subjective sleep quality (Pittsburgh Sleep Quality Index). Insomnia (Insomnia Severity Index). Actigraphy measure. Side-effect questionnaire (e.g., change in appetite measured on 7-point Likert scale).	Warning participants did not experience a reduction in self-reported insomnia symptoms while the no warning participants did. Participants that were warned reported they slept less than participants that were not warned, but there was no difference on objective measures. Significant changes in appetite in line with the warnings, but only for	Sample size likely underpowered for analyses (individual group n's not reported).

				information but received no warning regarding potential side-effects. Participants were further split into: no warning with placebo treatment and no warning without placebo treatment.		participants that received the placebo treatment than participants that did not.	
Psychological Outcome Context							
de Wied, Hoffman, and Roskos-Ewolden (1997)	Conducted in United States of America. Psychological outcome context: suspense in response informed consent.	Randomised 2 (warning: violent warning, non-violent warning) x 2 (gender: male, female) x 2 (film type: The Killing Fields, Once Upon a Time in the West) mixed, pre- and post-design.	*N* = 96. 57 female and 38 male undergraduate students.*	Condition 1: participants received consent information that explained the film they were about to see had been rated R but that all violent elements had been edited out of the film. Condition 2: participants received consent information that explained the film was rated R due to explicit graphic violence. Participants were also informed that the film received this rating before more graphic violence was allowed in films and if they thought viewing they film would be troublesome for them, they should discontinue participation.	Ratings of suspense and emotions related to the film clip (e.g., tense, worried, anxious). Note, these ratings were factor analysed and broken down into distress and entertainment. Trait empathy (empathetic sensitivity measure).	Participants in Condition 2 reported significantly more distress and were scared they would see something they did not want to see, in comparison to Condition 1.	No control condition which limits causal conclusions. Small sample size without a priori sample size justification.
Bussell (2017)	Conducted in United States of America. Psychological outcome context: participant distress in response to consent. Doctoral thesis.	Randomised 2 (warning type: harsh warning, lesser warner with benefits emphasised) x 2 (measurement type: self-report, interview) between-subjects design.	*N* = 120. Half females (*n* = 60) and half males (*n* = 60). M_{age} = 38.1 (*SD* = 14.42). Participants were excluded if: they had experienced a recent trauma, had active suicidal	Condition 1: participants received consent information that presented associated risks of participating using harsh language (e.g., "If you have trauma related stress symptoms, you may have an increase in nightmares or flashbacks related to your traumatic experience.").	PTSD symptoms (PTSD checklist for DSM-5). Trauma history (Trauma History Screen). Depression symptoms (Center for Epidemiologic	Significant 2 (warning type) x 2 (measurement type) interaction, but only for participants who self-reported on measures. Participants in the self-report condition reported more PTSD and Depression symptoms when harshly warned versus receiving a lesser	No a priori justification for sample size. No baseline measurement of trauma history. No true control condition which

			ideation or a past suicide attempt.	Participants were further split into: harsh language self-report and harsh language interview. Condition 2: participants received consent information that presented associated risks of participating using a lesser warning with the benefits emphasised (e.g., "There is a chance that some of the questions might cause distress, but that is very rare and typically those feelings do not last very long."). Participants were further split into: lesser warning self-report and lesser warning interview.	Studies Depression Scale-Revised). Dissociative symptoms (Dissociative Experiences Scale-Brief). Reactions to research participation (Reaction to Research Participation Questionnaire Revised).	warning. However, these patterns did not hold for the interview condition. Moreover, when self-reporting, participants in the harshly warned condition reported significantly fewer traumatic events on the trauma history screen than the interview condition.	limits causal conclusions.
Senn and Desmarais (2006; Study 1)	Conducted in Canada. Psychological outcome context: participant evaluation of stimuli and response to consent.	Randomised 3 (consent form: procedure only, procedure plus some content, procedure with detailed content highlighting stressful elements) x 3 (slide content: erotica, non-violent pornography, violent pornography) between-subjects design.	N = 135 female undergraduates. M_{age} = 22.93 (SD = 5.92).	All participants viewed a consent form with the same information, barring the following: Condition 1: participants received consent information that detailed the procedure only (e.g., "You will fill out a number of measures asking you about your background and your personal experiences.") Condition 2: participants viewed consent information regarding the study's procedure, as well as the type of content they will see (e.g., "The slides may contain sexually explicit and/or violent content…")	State mood (Profile of Mood States). Pre-study expectations (e.g., "What are you expecting to be asked based on what you have been told so far?"). Post-study expectations (e.g., "Were the slides what you expected?). Slide content ratings (Semantic Differential Scale; e.g., good to bad, kind to cruel).	Participants in Conditions 2 and 3 rated the slide content as significantly more negative than participants in Condition 1. No effect on consent form type on state mood. No effect of consent form type on participant interest, ratings of scientific value, or willingness to volunteer again. No effect of consent form type on pre- or post-expectation measures.	Only included female participants. Analyses were likely underpowered (e.g., 3 x 3 ANOVA) given sample size.

				Condition 3: participants received details regarding the procedure and any stressful elements of the study (e.g., "These images may be upsetting or objectionable to some people.")	Reactions to participation (e.g., participant interest, scientific value, and willingness to volunteer again).		
Senn and Desmarais (2006; Study 2)	As above.	Randomised 3 (consent form: procedure only, procedure plus some content, procedure with detailed content highlighting stressful elements) between-subjects, pre-post measure design. Note, participants answered sensitive questionnaires in Study 2 rather than viewing potentially sensitive content.	N = 75 female undergraduates. M_{age} = 20.73 (SD = 2.14).	All participants viewed a consent form with the same information, barring the following: Condition 1: participants received consent information that detailed the procedure only (e.g., "You will fill out a number of measures asking you about your background and your personal experiences.") Condition 2: participants viewed consent information regarding the study's procedure, as well as the type of questions they will answer (e.g., "Some of the questions are requests for information about your positive and negative sexual experiences…" Condition 3: participants received details regarding the procedure and any stressful elements of the study (e.g., "Some of these questions are of a highly personal nature…If for any reason you do not feel that this is a study you can participate in, please feel	State mood (Profile of Mood States). Pre-study expectations (e.g., "What are you expecting to be asked based on what you have been told so far?"). Post-study expectations (e.g., "Were the content of the questions as you expected?). Attitudes towards consensual and coercive sexual experiences, sex education, etc. Reactions to participation (e.g., participant interest, scientific value, and willingness to volunteer again).	No significant effects on any measures (e.g., mood, expectations) for any consent conditions.	As above.

				free to leave now without continuing.")			
Fleming (1997)	Conducted in the United States of America. Psychological outcome context: side-effects of hypnosis in response to consent. Doctoral thesis.	Randomised 3 (consent form expectancy statement: few participants, 20% of participants, 50% of participants) x 3 (hypnosis susceptibility: low, medium, high)	*N* = 257 undergraduate psychology students; 169 females and 88 males.*	All participants received the same consent form, except for the following information: Condition 1: participants received a consent form that explained, "…it appears that a very few of participating participants report that they had experienced mild, short-term aftereffects…" Condition 2: participants viewed consent information that detailed, "…it appears that about one-fifth or 20% of participating participants report that they have experienced mild, short-term aftereffects…" Condition 3: participants received consent information that explained, "… it appears that about one-half or 50% of participating participants report that they have experienced mild, short-term aftereffects…"	Hypnotic susceptibility. Hypnosis experiences and side-effects.	Participants with low, medium, and high hypnotic susceptibility reported significantly increasing negative effects, which was greater at each preceding level. Participants with high hypnotic susceptibility in Condition 3 reported more negative effects than participants in Conditions 1 or 2. Overall pleasantness was more neutral for participants warned about 'smaller' aftereffects (i.e., Conditions 1 and 2), while participants in Condition 3 rated the overall experience as more negative.	Unpublished doctoral thesis. Unclear results for informed consent manipulation; no main effects reported.

* Mean age (and standard deviation) missing.

Experimental Conditions. All studies manipulated the presentation of associated risk and/or side-effect consent information using framing effects (i.e., information that is presented in a particular way that does not promote objectivity; Levin et al., 1998). Most studies used *attribute framing* whereby information appears according to the likelihood that an outcome will occur, framed via valence, either positively (i.e., will not) or negatively (i.e., will*;* Barnes et al., 2019, however see Levin et al., 1998 for stricter definition of attribute framing). In one example, Neukirch and Colagiuri (2015) warned one group of participants that people "…report *experiencing* a decrease[/increase] in appetite…" following their sham pill for sleeping difficulties (i.e., negatively framed), while the other condition received no information regarding side-effects. Similarly, Holzhüter and Hamann (2020) warned one group of participants that "…side-effects can *occur*…around 30% of all patients report dry mouth…", while the other condition received no framed information regarding side-effects. Myers and colleagues (1987) warned two groups of participants that side-effects from treatment included "…occasional gastrointestinal irritation…" (i.e., negatively framed), while the other group was informed, "…may develop a tendency to bleed but the risk of serious haemorrhage is extremely unlikely" (i.e., somewhere between negative and neutral framing).

Heisig and colleagues (2015) adopted a somewhat varied framing approach, choosing to emphasise the *benefits* of a potential cancer treatment or not. However, among those participants who did not receive emphasised benefits, it is unclear whether they received risk information or no information about benefits or risks. Wilhelm and colleagues (2018) also used a variation of attribute framing—termed positive message framing (Barnes et al., 2019). They positively framed side-effects of the placebo pill as the pill *working,* "If you become *dizzy* after taking the medication, it means your body is responding *particularly well…*", relative to negative message framing (i.e., termed neutral framing group in their paper), "This [dizziness] is a potentially unpleasant, but already known side-effect…".

Outcomes Measured. The studies tended to directly measure associated risks/side-effects that participants were warned about during consent (e.g., Heisig et al., 2015; Holzhüter & Hamann, 2020; Wilhelm et al., 2018). Some studies included related—but not necessarily direct—measures of associated risks/side-effects, such as self-reported sleep quality (Holzhüter & Hamann, 2020), psychological outcomes (i.e., anxiety; Heisig et al., 2015), and beliefs about medication (Wilhelm et al., 2018). Further, several studies used objective outcome measures, such as actigraphy, ECG, and/or a physical examination (Myers et al., 1987; Neukirch & Colagiuri, 2015; Wilhelm et al., 2018), meaning self-reported side-effects could be verified; that is, researchers could also examine whether the warning at consent led to *physiological* changes in line with the expectancy and nocebo effect.

Main Results. Just over half of the medical-outcome studies reported statistically significant results[34] for consent form manipulation and direct outcome measure(s) (i.e., measures that aligned with side-effects participants were warned about at consent), suggesting either the presence of negative expectations or of nocebo effects. Myers and colleagues (1987) aimed to examine medication side-effects among a convenience sample with unstable angina. Two groups of participants read consent forms detailing *minor* gastrointestinal (GI) side-effects while another group did not receive this specific warning; the differences in warnings reflected IRB requirements between two different data collection locations. Participants informed of *minor* GI side-effects not only reported more GI side-effects than participants not specifically warned about minor GI side-effects, but they were also more likely to withdraw from the treatment *because of* the side-effects. In another example, Neukirch and Colagiuri (2015) found participants warned about increases or decreases in appetite (counterbalanced within the same condition), reported either increases

[34] Note, we focus on statistical significance because several studies did not report effect size and/or we calculated effect sizes reported here ourselves. We report effect size(s) where possible.

or decreases in appetite—in line with the warning they received—relative to those who did not receive a warning. But whether such effects would be considered consistent with the definition of nocebo effects—that is, an adverse or negative outcome—is debatable because changes to appetite in either direction may be either a positive or negative outcome, dependent on the person. Heisig and colleagues (2015; Study 1) found that participants who received information emphasising the *benefits* of an imagined cancer treatment—versus participants who viewed information that did not emphasise the benefits of the cancer treatment—reported lower side-effect *expectations* ($\eta^2_p = 0.08$; small-to-medium effect) for the three most common side-effects associated with endocrine therapy (per the General Assessment of Side-Effects Scale; side-effect severity, *0 = not present to 3 = severe*; Rief et al., 2011). Of note however is that the authors did not report what participants in the "no benefits emphasised" condition *actually* read—including whether it contained risk information—at consent. Finally, two of the five medical studies reported no statistically significant differences between the consent form manipulation conditions (e.g., positive framing versus negative—i.e., termed neutral for the purposes of their study—framing) on the *direct* outcome measure (e.g., dizziness as a side-effect, participant expectations; Heisig et al., 2015, Study 2; Holzhüter & Hamann, 2020; Wilhelm et al., 2018). Wilhelm and colleagues did however report a small-to-medium effect size for their direct outcome measure ($d = 0.40$), as did Holzhüter and Hamann ($d = 0.56$).

Limitations. There are several notable limitations of the medical outcome studies. First, and perhaps most importantly, there are issues with the believability of the experimental manipulations (e.g., Heisig et al., 2015; Wilhelm et al., 2018). For example, Holzhüter and Hamann (2020) used an open-label procedure which—while perhaps helpful for IRB approval—presents difficulties in creating a potent expectancy manipulation, given participants know they are not receiving an active treatment. There is limited evidence

showing nocebo effects occur during open-label procedures (e.g., Meijer et al., 2021), thus it is difficult to know if an open-label procedure is an effective manipulation, particularly given that few studies in this review included manipulation checks. The lack of manipulation checks reduces the internal validity of these studies and subsequent conclusions we can draw. Second, four studies were likely underpowered to detect even small effects, given their sample sizes and the analyses they ran (t-tests and between-subjects ANOVAs; Neukirch & Colagiuri, 2015; Heisig et al., 2015; Holzhüter & Hamann, 2020; Wilhelm et al., 2018). For example, Wilhelm and colleagues (2018) report their key findings using one-tailed t-tests, as well as two-tailed t-tests, with $N = 80$, ds = 0.12 to 0.40. A sensitivity analysis using G*Power (Version 3.1) reveals that Wilhelm and colleagues could reliably detect effects at $d = 0.63$ (two-tailed) and $d = 0.56$ (one-tailed), given $\alpha = .05$, 80% power, and 40 participants per condition. However, Wilhelm et al.'s reported effect sizes fall below 0.63 and 0.56, suggesting that the sample size was not sufficient to detect reliable effects (Perugini et al., 2018). From an ethical standpoint and in the case of nocebo effects, detecting even *small* effects is important because it indicates the magnitude of harm that people may be exposed to due to risk-warnings, and hence the level of change needed to ethical guidelines. Finally, because Myers and colleagues (1987) did not randomly allocate participants to condition, the internal validity of the study is low, meaning we cannot confidently attribute the reporting of withdrawal of people with minor GI symptoms to the warning received.

Psychological Outcome Settings

Overall, the four psychological outcome studies had different foci: one concentrating on suspense as the nocebo effect (de Wied et al., 1997), one on distress (Bussell, 2017), another on evaluations of sensitive stimuli/questionnaires (Senn & Desmarais, 2006), and finally, one on side-effects of hypnosis (Fleming, 1997).

Sample characteristics were somewhat consistent: sample sizes ranged (i.e., 75-257) and mean reported age from 20.73 to 38.1 years. All studies included all genders, excluding Senn and Desmarais (2006) who studied females only. All four studies relied on undergraduate samples, thus understanding of consent risk-warnings and nocebo effects in a psychological outcome setting is restricted to this sample type, with effects in other sample types unknown.

Experimental Conditions. Again, all psychological outcome studies used different framing effects to manipulate risk information. We identified most studies as using attribute framing: in one condition participants were told "…you may have an *increase* in nightmares or flashbacks…" (i.e., negative framing), while the other condition was informed "…might cause distress, but that is very rare…" (i.e., positive framing; Bussell, 2017). Participants were either informed that "…*very few*…participants report that they have experienced mild, short-term aftereffects…" (i.e., positive framing; low likelihood), "…*one-fifth* or *20%*..." (i.e., somewhat negative framing; moderate likelihood), or "…*one-half* or *50%*..." (i.e., negative framing; high likelihood; Fleming, 1997). Participants either received neutral framing (e.g., about the procedure only, "You will fill out a number of measures…"), somewhat negatively framed (e.g., about the procedure *and* the content type, "The slides may contain sexually explicit and/or violent content…") or negatively framed consent information (e.g., "These images may be upsetting or objectionable to some people"; Senn & Desmarais, 2006). Further, de Wied and colleagues (1997) warned participants that "…the movie segment they were about to see had been rated R, but all violent elements had been edited out of the movie" (i.e., positive framing) or the "…movie had been rated R because of explicit graphic violence…had received the R rating when more graphic violence was allowed in movies than currently was the case…if viewing explicit violence was troublesome, they should discontinue their participation in the experiment" (i.e., negative framing).

Outcomes Measured. All four psychological outcome studies directly measured associated risks/side-effects that participants were warned about at consent (e.g., some participants were warned about sexually explicit slide content being upsetting/objectionable and then participants rated the contents of these slides; Senn & Desmarais, 2006). Only one of the four studies measured participants' expectations following the risk-warning at consent (Senn & Desmarais, 2006). Because people's expectancies play an important role in nocebo effects (Montgomery & Kirsch, 1997; Webster et al., 2016), it is important to measure *both* expectancy and nocebo effects to gain greater understanding of the effects risk-warnings may have (e.g., the difference between negative expectancies compared to negative outcomes/nocebo effects). Further, two studies included measures designed to capture outcomes *related to* the primary risk participants were warned about at consent (e.g., depression symptoms, reactions to research participation; Bussell, 2017; Senn & Desmarais, 2006). It is possible that risk-warnings—for example, an increase in intrusive memories—may not affect depression directly, but may affect emotions such as sadness and PTS symptoms that may go on to influence depression (Bussell, 2017). Thus, measuring outcomes *related* to the primary risk can be useful. No study incorporated physiological outcome measures.

Main Results. Overall, all studies reported statistically significant differences for consent form manipulation and direct outcome measure(s), indicating nocebo effects. de Wied and colleagues (1997) found that participants who received a warning that film content contained graphic violence with an "R" movie rating reported significantly more distress and were afraid they would view something in the footage that they did not want to see, relative to participants who were told that all the violent film elements were edited out. Similarly, participants who received a risk-warning using "harsh language" had higher scores for PTSD symptoms (i.e., direct outcome measure; $d = 0.52$) and depression symptoms (i.e., associated

outcome measure; $d = 0.62$), compared to participants who received a lesser warning that emphasised benefits; though this finding was applicable only to participants who self-reported via questionnaires and not those who answered questionnaires via interview ($\eta^2 = 0.06$; Bussell, 2017).

Senn and Desmarais (2006) reported mixed findings. In Study 1, participants who viewed warnings about the slide content (e.g., sexually explicit content) or warnings about the slide content and any stressful elements (e.g., images may be upsetting) rated the slide contents as significantly more negative than participants who only received information about the study's procedures (e.g., measures will ask about your background). But there was no effect of consent form on the state mood measure, pre- or post-expectation measures (i.e., direct outcome measures) or reaction to research questions (e.g., participant interest, scientific value, and willingness to participate again; i.e., *associated* outcome measure). In other words, nocebo effects were present for people's evaluations of how negative the slide content was; but warnings did not influence participant's expectations (e.g., their expected interest in the study, familiarity with the images). Moreover, warnings related to participants' emotional reactions (e.g., may be upsetting) did not seem to translate to effects on mood, nor did any of the elements of consent warnings influence participants' reactions to participation. In Study 2, rather than rate slide content, participants answered questionnaires related to their attitudes toward sexual-related issues (e.g., consent, coercive sexual experiences, sex education). Consistent with Study 1, there were no significant differences for consent form type on state mood or expectation measures.

Finally, Fleming (1997) found an effect of consent warning type on reported side-effects, depending on participants' hypnotic susceptibility (i.e., how likely someone is to experience hypnosis). Participants reported significantly increasing negative side-effects[35]

[35] Note, Fleming (1997) did not report specific side-effects, only side-effects generally.

across the low likelihood, moderate likelihood, and high likelihood warning conditions. Put differently, reported negative side-effects were greatest in the high likelihood condition, followed by the moderate then the low likelihood conditions. However, this finding was only for participants with high hypnotic susceptibility. Additionally, participants in the high likelihood condition reported the overall hypnosis experience as *more* negative than the moderate likelihood or low likelihood conditions, who rated the experience as more *neutral.*

Limitations. There are several limitations of the psychological outcome studies. Few studies used a true control condition (i.e., a condition that received *no warning*) to compare warnings against (e.g., Bussell, 2017; de Wied et al., 1997; Fleming, 1997). This issue in methodological design limits our ability to examine whether nocebo effects are present, relative to receiving no warning at all. Recall that in the medical outcome studies, a notable limitation was inappropriate sample sizes for the analyses used; this limitation also applied here, for most analyses (de Wied et al., 1997; Fleming, 1997; Senn & Desmarais, 2006, Study 2), excluding Bussell (2017) and Senn and Desmarais (2006, Study 1). Two of the four studies were unpublished doctoral theses that had issues in the clarity of reported results (e.g., missing statistical information, unclear language and/or explanations; Fleming, 1997) and methodological limitations (e.g., conclusions hinging on measures only collected at one point in time; Bussell, 2017), perhaps because no peer review occurred.

Discussion

The current review aimed to summarise how past literature has quantitatively examined nocebo effects and negative expectancies resulting from risk-warnings provided at the time of consent. Following the JBI methodology for scoping reviews (Tufanaru et al., 2017), we identified only nine empirical works that met criterion for inclusion; of these, five studies focused on medical outcome settings and four on psychological outcome settings. Our review documents the varied empirical approaches researchers have taken toward

understanding the risk of negative expectancies and nocebo effects at the time of informed consent, as well as study findings. Hence, our review has several key implications for this important field of research.

Based on the findings of this review, the data on whether informed consent risk-warnings lead to nocebo effects is largely inconsistent across medical and psychological settings. In some cases, nocebo effects do appear to result from risk-warnings at informed consent. For example, participants report more dizziness when they are warned about this side-effect (Wilhelm et al., 2018), more GI symptoms when warned about these very same GI symptoms (versus no GI warning; Myers et al., 1987), and more distress when they are warned that a film will contain graphic violence (versus. violence having been removed from the film; de Wied et al., 1997). However, several studies fail to find a relationship between the risk-warning provided—including the side-effect framed either positively or negatively—and their direct outcome measure(s) (e.g., Holzhüter & Hamann, 2020; Senn & Desmarais, 2006, Study 2) or between the risk-warning and participant expectancies (e.g., Heisig et al., 2015; Senn & Desmarais, 2006). Thus, despite consistent evidence of nocebo effects within the medical outcome domain, and to a lesser extent, within the cognitive psychology area (e.g., via memory; Takarangi & Strange, 2010), whether nocebo effects occur because of a risk-warning given to participants *at the time of consent* remains unclear.

Limitations of the Field and Recommendations for Future Research

In part, the inconsistent findings likely stem from methodological differences within the studies identified here, which—while limiting the overall causal conclusions we can draw about nocebo effects and risk-warnings occurring at the time of consent—offer opportunities for future methodological improvement (see Supplementary Files at the end of this Chapter for summary of key recommendations). Overall, only a handful of studies incorporated a no warning control group (e.g., Holzhüter & Hamann, 2020). Including such a control group is

particularly important because differences between an active and control condition show not only whether a nocebo effect may be present, but also the magnitude of that effect (e.g., Bridgland & Takarangi, 2021). Certainly, where ethics is concerned, it is crucial to understand how meaningful the nocebo effect is within an informed consent context—if it is indeed consistently present—because such knowledge will indicate suitable solutions, including how much change to current consent practices may be necessary. For example, small effects may suggest a minor ethics guideline amendment (e.g., framing risks using frequency anchors, such as likely/unlikely), whereas larger effects—that result in larger consequences—may warrant major guideline changes (e.g., informing all participants what nocebo effects are prior to viewing the consent form; Crichton & Petrie, 2015).

It is possible that several of the studies included here had weak manipulations. Participants may have struggled to believe and apply the study's manipulation to themselves, such as in the two studies that used healthy participants to examine medical-based issues—including one study that used an imagined cancer scenario—(Heisig et al., 2015; Wilhelm et al., 2018), or in another study that used an open-label placebo procedure (Holzhüter & Hamann, 2020). Perhaps these manipulations were not strong enough to reveal nocebo effects. Of course, the use of such manipulations—particularly open-label procedures—assists in obtaining ethics approval, since it means deception need not be involved (e.g., NHMRC, 2018). However, these ethical considerations need to be balanced against the aim of rigorously examining whether nocebo effects occur because of informed consent risk-warnings; namely, by creating manipulations with sufficient believability to observe nocebo effects.

Relatedly, only one study reported a manipulation check to show that participants had read the warning that was included on the consent form (Bussell, 2017). Thus, it is unclear whether all participants read and understood the risk-warning manipulation. Indeed, we know

that participants generally do not read nor recall information in consent forms well (Douglas et al., 2021; Mann, 1994; McNutt et al., 2008). Manipulation checks could take the form that Bussell (2017) used, whereby participants had to initial each section of the consent form after the experimenter read it out to them, or checks could involve a short comprehension question that asks the participant to recount or select which warning they received and/or the expectations they had.

There is also notable inconsistency in the framing of risks between conditions within the same study. For example, Wilhelm and colleagues (2018) informed one condition, "If you become *dizzy* after taking the medication, it means your body is responding *particularly well…*", while the other condition was told, "This [dizziness] is a potentially unpleasant, but already known side-effect…", but overall, both conditions were told that "…symptoms occur in 10 out of 100 people…" (see also Holzhüter & Hamann, 2020). Thus, not only are multiple framing techniques applied across conditions within the same study—potentially confounding results—but manipulating the attribute (i.e., dizziness) using different approaches—in one case, that the placebo is working *particularly well* versus a *potentially unpleasant*, but *known side-effect*—creates difficulty in drawing causal conclusions. Indeed, Barnes and colleagues (2019) reported a similar issue of inconsistent framing used within the same study in their review of positive framing and the nocebo effect, concluding that it was difficult to interpret the effects of the inconsistent framing on results.

Further, there are issues with how researchers have measured direct outcomes (of the warned of associated risk/side-effect). In several studies, the key associated risk/side-effect that participants were warned about at informed consent (i.e., the framed attribute) was not clearly and directly measured. Instead, studies measured *overall* associated risks/side-effects, such as impairment caused by side-effects, rather than the specific side-effects participants were warned about, such as dry mouth, sweating, or vertigo (Holzhüter & Hamann, 2020; see

also de Wied et al., 1997; Fleming, 1997; Wilhelm et al., 2018). Not only does measuring *associated* risk/side-effects, rather than direct outcomes, create difficulties in assessing whether warning participants about a particular associated risk/side-effect led to nocebo effects, it also complicates comparisons across studies (Barnes et al., 2019). Again, such issues limit the strength of causal conclusions.

There were several issues with sample size and analyses used in multiple studies. Relatedly, few studies included evidence of an a priori sample size with justification for why that sample size was chosen (e.g., looking for smallest effect size, previously found effect sizes; Lakens, 2021), which is important because such justifications help us infer the study's usefulness (e.g., Holzhüter & Hamann, 2020). No studies were pre-registered. We of course acknowledge that pre-registration as a norm in psychology—if indeed it is now a norm (see Hardwicke et al., 2022; Norris et al., 2021)—post-dates these studies. However, pre-registration is an important step forward within this area of research to ensure transparency and accuracy by: stating hypotheses, choosing appropriate analyses to limit Type 1 error (e.g., see Wilhem et al., 2018 for discussion of one-tailed/two-tailed results), and directly answering research questions, with any deviations recorded (Lakens, 2017). Finally, few studies included detailed recording of and/or accessibility to consent materials. Particularly with the area of research at hand, having a comprehensive understanding of what previous researchers have exposed participants to, including the framing and presentation of all aspects of the consent process, is important. Indeed, we know that framing influences people's perception of information (e.g., Kahnemann & Tversky, 1979) and that participants have preferences for consent form presentation (e.g., bolding important information; Perrault & Keating, 2017). Thus, having a detailed understanding of how consent information is presented in each study is important to shape how future research approaches investigations

of consent and nocebo effects; ideally leading to improvement(s) to ethical guidelines and safeguarding participants' welfare.

Taken together then, future research will need to refine methodological design to promote internal validity. For example, we encourage researchers to use control conditions to help appropriately examine whether nocebo effects are occurring as a direct result of risk-warnings provided at the time of consent. By initially improving the internal validity of such studies (see Supplementary Files at the end of this Chapter for key recommendations)—and subsequently strengthening causal conclusions—we can then begin to explore additional factors, such as the effects of combined written and verbal consent risk-warnings, and triangulate research across multiple settings (e.g., research participation, health care settings; Lin et al., 2020).

Of course, there are limitations to the scope of this review and the subsequent conclusions we can draw. We strictly defined consent practices as those being when people are told all relevant information about a potential procedure, drug administration, or research experience, and then have to make a decision to either consent or not consent. But there are other consent situations that may be susceptible to nocebo effects, such as when a patient has previously consented to a procedure and the health practitioner is verbally advising the person about the procedure as it is occurring (e.g., how much pain to expect from a needle; Varelmann et al., 2010). Our review also only considered quantitative studies—that is, experimental, quasi-experimental, and analytical observational studies—which means potentially informative qualitative evidence, such as case studies, are absent from the present discussion. Finally, there are other factors relevant to nocebo effects that the current review does not consider, such as people's past experiences or personality type (Webster et al., 2016), which may contribute to the nocebo effect's occurrence.

Conclusion

The potential nocebo effects resulting from informed consent procedures is widely discussed by researchers and ethicists (e.g., Cohen, 2014; Colloca, 2017; Fortunato et al., 2017; Loftus & Fries, 2008; Michael et al., 2012; Wells & Kaptchuk, 2012), and of course, is of great concern to these groups, as well as to those responsible for safeguarding participant and patient wellbeing (i.e., IRBs). Despite consistent research detailing nocebo effects across medical and psychological contexts (e.g., Assefi & Garry, 2003; Michael et al., 2012; Mitsikostas et al., 2014; Petersen et al., 2014; Takarangi & Strange, 2010), evidence for nocebo effects directly resulting from informed consent is limited, and several methodological limitations constrain the strength of causal conclusions. We hope our review can serve as a reference point for how previous studies have *quantitatively* examined the relationship between negative expectancies and nocebo effects *at the time of consent,* as well as provide guidance for future research in this area.

Supplementary Files

Search Strategy

The search strategy will aim to locate both published and unpublished studies. An initial limited search of PsycINFO and MEDLINE was undertaken on 17th June 2021 to identify relevant articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for PsycINFO. The search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. The reference list of all included sources of evidence will also be screened for additional studies.

Due to time and resource constraints, we will only include studies published in English. We will not limit studies to a particular date range.

Search conducted using PsycINFO on 17th June 2021.

Search	Query	Records Retrieved
#1	(informed consent or informed consent procedures or consent forms or consent form).ab,ti	8464
#2	(nocebo effects or nocebos or side-effects or negative placebos or negative expectancies or negative expectations).ab,ti	30659
#3	(suggestion or verbal suggestion or suggestibility).ab,ti	17521
#4	(warnings or risk warnings or trigger warnings).ab,ti	2777
#5	1 and 2	202
#6	1 and 3	22
#7	1 and 4	17
#8	1 and 2 and 3	1
#9	1 and 2 and 4	4
#10	5 or 6 or 7 or 8 or 9	236
*#10 restricted to English only (223 records retrieved)		

Table S7

Key Recommendations for Future Research

Recommendation
1. Use a no warning control condition—or equivalent—to compare effects against participants who receive different warning types (e.g., low risk-warning, high risk-warning, positively valenced warning, negatively valenced warning).
2. Consider strategies to increase the strength of warning manipulations (e.g., applying medical-based warnings to people who have the condition rather than healthy people, avoiding open-label procedures).
3. Include some form of manipulation check, such as asking participants a question about the specific warning, to ensure that participants have read/heard the warning of associated risks/side-effects.
4. Where possible, consistently frame conditions (e.g., one condition has *will,* the comparison condition has *will not*; one condition contains the percentage of people that do experience an associated risk/side-effect and the comparison condition details the percentage of people that do not experience an associated risk/side-effect).
5. Provide an estimate for desired sample size, as well as justification for the sample size.
6. Adhere to open science practices by pre-registering studies (e.g., hypotheses, planned analyses, deviation from analysis plan), and making materials and data available.
7. Include consent materials in manuscripts, supplementary materials, or online.
8. Expand studies to different populations (e.g., outside Westernised countries) and different demographics (i.e., expand beyond undergraduate population).

Chapter 8: Expecting psychological side-effects: Do informed consent risk-warnings in trauma-related research change participant expectancies?

Author contributions: I developed the study design with the guidance of MKTT and VMEB. I collected and cleaned the data, and performed the data analysis and interpretation. I drafted the manuscript and MKTT and VMEB provided critical revisions. All authors approved the final version of the manuscript for submission.

Abstract

Consent risk-warnings are used in psychological trauma-related research to convey risks—or side-effects (e.g., distress)—associated with participation. But these warnings may cause participants to experience the side-effects, or negative outcomes, they are warned about (i.e., nocebo-type reaction; Benedetti et al., 2007), with the first step in this chain reaction being *negative expectations* (e.g., Rooney et al., 2023). Thus, across two online experiments (Experiment 3a: $N = 200$; Experiment 3b: $N = 300$), we compared participants' expectancies (e.g., for distress) after encountering different risk-warnings during informed consent procedures. Although we found some evidence—in Experiment 3b—to suggest risk-warnings change participants' negative expectancies, overall, participants generally *disagreed* that they expected to experience warned of side-effects. Hence, while it is unlikely consent risk-warnings are causing harm, they are likely not working as intended (e.g., risk-warnings should change people's expectancies for side-effect risk information). Our findings have implications for how IRBs and trauma researchers use informed consent risk-warnings in psychological research.

Introduction

"Psychological questions about negative life experiences…bring up painful emotions. These emotions include sadness, worry, or increased anxiety…" (Bussell, 2017). Researchers use such risk-warnings in psychological trauma-related research to communicate risks to

participants (e.g., Abu-Rus et al., 2019). When used as intended, these risk-warnings show respect toward participant autonomy and should protect people from potential harms by upholding the *beneficence* principle (e.g., NHMRC, 2023). But some researchers have raised the possibility that these well-intentioned risk-warnings may cause participants adverse outcomes (e.g., psychological distress) via a *nocebo reaction* (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006). The first step in a nocebo reaction chain would be that the psychological side-effects *suggested* via a risk-warning lead participants to develop negative expectations about their reactions to participating in the research (e.g., Colloca, 2024; Rooney et al., 2023; Webster et al., 2016; see also Kirsch 1985 for *response expectancy*). Thus, here, we examined whether different consent risk-warnings changed participant expectancies for warned of side-effects.

IRBs are tasked with determining risks associated with psychological trauma-related research. This task is likely challenging, because trauma is subjective (e.g., McNally, 2003), and aside from a small literature investigating participant reactions to trauma-related research (e.g., Jaffe et al., 2015), empirical data are limited (e.g., rates of people reporting participation side-effects). Hence, IRBs likely use subjective or intuitive methods—including their own experiences or imagining themselves as participants—to judge risk (e.g., Carter-Visscher et al., 2007; Haggerty, 2004; Smith & Anderson, 2022). But these methods may cause inaccurate risk judgments (e.g., base rate errors due to believing most people will be distressed by participation when evidence suggests this is unlikely; Jaffe et al., 2015; Newman et al., 2006), and to IRBs *overestimating* trauma-related research risks (Abu-Rus et al., 2019). Indeed, in over one-third of 180 dissertations containing psychological trauma-related research, the consent forms presented participation risks as *severe* (Abu-Rus et al., 2019). Yet, graduates—likely more knowledgeable about trauma-related research and associated psychological risks (e.g., age, sample type)—coded these consent forms as mild-

to-moderate risk (Abu-Rus et al., 2019). Therefore, we can infer that risks are often overstated to participants in psychological trauma-related research (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006).

One concerning possibility is that overstated psychological risks contribute to negative outcomes for participants (compared to being unwarned and/or encountering a less severe warning; e.g., Abu-Rus et al., 2019; Bridgland & Takarangi, 2021; Loftus & Teitcher, 2019; Stirling et al., 2023). Warning participants about a negative outcome—like experiencing anxiety—could serve as a negative *suggestion* (e.g., Webster et al., 2016), causing participants to *expect* a negative outcome (Rooney et al., 2023). This expectancy may lead participants to manifest that negative outcome, for instance, experiencing anxiety (i.e., nocebo effect; e.g., Barsky et al., 2002; Benedetti et al., 2007; Geers et al., 2021); an outcome that may not have occurred if participants encountered no warning.

Indeed, the extant medical-based nocebo effect literature indicates that suggested side-effects, whether presented specifically during the informed consent process or not, cause nocebo effects (e.g., Colloca, 2024; Barsky et al., 2002; Myers et al., 1987). For example, a systematic review identified that giving participants *explicit suggestions* that they will experience arousal and/or symptoms predicts them then showing nocebo effects (Webster et al., 2016). In one example, online participants who encountered written information about the side-effects of low frequency noise exposure—and were subsequently exposed to low frequency noise—were significantly more likely to expect side-effects and actually report those side-effects (e.g., headaches), than participants who did not receive side-effect information (Barnes et al., 2023). Thus, prior nocebo effect research connects the informed consent process—where side-effect warnings are similar to risk-warnings (Abu-Rus et al., 2019)—to nocebo effects.

Response expectancy provides one explanation for how nocebo effects arise from suggestions about side-effects and risks (Kirsch, 1985). When people anticipate their own automatic behavioural reactions, they execute a chain of behaviours that inadvertently brings about those reactions (Kirsch, 1985). For instance, expecting to feel alert after consuming coffee or to experience warned of medication side-effects (e.g., GI side-effects) leads to these expected outcomes (e.g., Kirsch, 1985; Myers et al., 1987). There is also empirical support for *negative expectations* as a primary nocebo effect mechanism (e.g., Benedetti et al., 2007; Colloca, 2024; Rooney et al., 2023, though see Petrie & Rief, 2019 for other mechanisms beyond this paper's scope). For instance, participants given negative treatment suggestions during saline IV administration (e.g., IV drip will increase pain sensitivity) reported greater pain expectations (versus positive/truthful suggestions; Elsenbruch et al., 2019). There is however limited research that tests response expectancy as an explanation for potential nocebo effects arising from consent risk-warnings in *psychological* settings.

Specifically, the published research examining how consent risk-warnings influence *psychological* outcomes has produced mixed findings, with only one study measuring participant expectations (Senn & Desmarais, 2006; Stirling et al., 2023). In one example, participants warned that an upcoming film contained violent material—versus participants told the violent material had been edited—reported more distress post-film (i.e., nocebo effect; de Wied et al., 1997). But another study found no evidence of nocebo-type responding after participants encountered different consent risk-warnings (e.g., procedure-only, explicit warning; Senn & Desmarais, 2006). Additionally, risk-warning type did not affect participant expectancies, except in Study 2, where people who encountered a stressful/personal-focused warning were more likely to report that study questions did not match their expectations (Senn & Desmarais, 2006). Given these mixed—and limited—findings, it is unclear whether consent risk-warnings change participant expectancies, let alone cause nocebo effects.

Turning to the literature on trigger warnings (i.e., alerts that supposedly help people prepare and avoid upcoming material that may trigger memories/reactions connected to prior experiences; Bridgland et al., 2023), some evidence indicates warnings change participant expectancies. In two experiments, participants who viewed a trigger warning about potentially negative content expected subsequent films (Sanson et al., 2019) and photographs (Bridgland et al., 2019) to be more negative (versus unwarned participants). Further, a recent meta-analysis showed participants report increased anticipatory anxiety *after* encountering a trigger warning, but prior to viewing warned of—potentially negative—content (d = 0.43; Bridgland et al., 2023). However, there are limitations to generalising these findings to *informed consent* risk-warnings. First, the warnings were not part of the consent process. Instead, participants completed consent procedures, viewed their respective warnings, and responded to psychological measures (e.g., anxiety). Second, these studies measured expectancies related to the study/content itself (e.g., how negative the upcoming film will be; Sanson et al., 2019; Senn & Desmarais, 2006), rather than personal reactions to participation. Finally, trigger warnings may be attached to an evolving cultural understanding (e.g., their use in a classroom might suggest an instructor is part of a social clique with their students; Bridgland et al., 2023) that changes how people interpret the term. Yet, consent risk-warnings might not be linked in the same way to a cultural understanding. Thus, consent risk-warnings may not change participant expectancies in the same way as trigger warnings.

In summary, few empirical studies directly examine how consent risk-warnings—provided, experimentally, during the consent process—influence participant expectancies. Moreover, to date, no published research has investigated whether consent risk-warnings used in *psychological trauma-related research* cause negative outcomes for participants (though see Bussell's 2017 doctoral thesis), or change participants' expectancies (Stirling et al., 2023). Thus, we investigated whether different consent risk-warnings—*presented during*

the consent process in a psychological trauma-related study—changed people's expectancies regarding anticipated psychological side-effects.

We operationalised our nocebo-effect chain reaction as: providing participants with different informed consent risk-warnings (i.e., *suggestion*) and asking them whether they expected to experience potential psychological side-effects (i.e., *expectancy measure*). For ethical reasons, we did not measure the final step in this chain (i.e., psychological outcomes, like distress). Instead, we focused on the first step because we could provide participants with any warning type and not need to expose them to negative content without adequate information and/or supports.

We recruited participants online and presented them with one of two (Experiment 3a) and one of three (Experiment 3b) risk-warnings. We measured their expectancies via anticipated emotion (e.g., "I expect to feel distress") and anticipatory anxiety (e.g., responding to items such as "I feel tense"). In Experiment 3a, we had two pre-registered predictions. First, we predicted that participants exposed to the high risk-warning would report higher anticipatory anxiety immediately after viewing the warning, relative to participants who viewed the negligible risk-warning. Second, we expected that after viewing the high risk-warning, participants would anticipate feeling more distressed, upset, anxious, and afraid; anticipate more ongoing psychological distress, difficulties sleeping, and distressing memories (i.e., higher mean scores) than participants exposed to the negligible-risk-warning.

Experiment 3a

Method

We pre-registered Experiment 3a and 3b on the OSF (Experiment 3a: https://osf.io/geytn, Experiment 3b: https://osf.io/u847x), where the data are publicly available (https://osf.io/ag52n/). We report all conditions, measures, and data exclusions. Given the ethically challenging nature of this research, we also include our risk-management

protocol to assist other researchers in their study design (see Supplementary Files at the end of this Chapter or https://osf.io/ag52n/). The Flinders University Human Research Ethics Committee approved this study.

Participants

Per pre-registration, we aimed to collect 200 participants. Using G*Power (Faul et al., 2007), we powered to detect small-to-medium effects (i.e., 0.4 and above) at 80% power and $\alpha = .05$ (see also Brysbaert, 2019). We based this decision on the idea that risk-warnings form an important part of the consent process, and therefore, evidence for risk-warnings causing negative expectancies—and inciting subsequent policy change—would need to be strong (i.e., not of small effect).

We recruited 208 US-based participants from MTurk (see https://osf.io/geytn for worker criteria). We excluded four participants for not believing they would view a traumatic film, two participants for responding to open-text questions in ways consistent with bot responding (e.g., "good," "film"), one participant for guessing our study aim, and one participant for responding incorrectly to the cultural check question (see Moeck et al., 2022). Thus, our final sample was $N = 200$. Our sample was aged $M = 41.15$ ($SD = 11.36$), roughly half men (50.5%; women: 48.5%, non-binary: 0.5%, prefer not to say: 0.5%), and mostly self-reported as white/Caucasian (70%; black/African American: 11.5%, Asian: 8.5%, Other [Native Hawaiian, Indian, Korean, Chinese, Indigenous American, Pacific Islander, or "homo sapien"] 4%, Mixed: 2.5%, Latino: 1.5%, Hispanic: 1%, and Filipino: 1%). Almost half (47%) our sample's highest education level was a bachelor's degree, followed by high school/equivalent (22%), associate degree/diploma (15%), master's degree (13%), and doctoral studies (3%). Participants were compensated US $1.20.

Materials

Risk-Warning Conditions (Appendix E). Participants viewed one of two information and consent forms: one contained a high risk-warning (i.e., "Because this study will involve watching graphic scenes depicting blood, injury, explicit physical or sexual violence or death, participants may experience feelings of distress [e.g., upset, afraid, or anxious]. Participants may also experience distressing memories in the week after watching the film clip, as well as difficulties sleeping"); one contained a negligible risk-warning (i.e., "There is negligible risk to you when completing this study"; see https://osf.io/ag52n/ for the consent forms in full). We used a negligible warning to provide participants with some form of risk statement without warning them of potential side-effects. The information and consent forms were otherwise identical. Participants listened to a short audio-recording reiterating the study's purpose and associated risk (i.e., high-risk or negligible risk-warning). To divert attention away from our true purpose, we told participants that our IRB required they listen to the short description because the study involved viewing a trauma film clip. Note that participants never viewed the film clip; we only had them believe they would.

State Trait Anxiety Inventory Short Form (STAI-6; Marteau & Bekker, 1992; Appendix F). To examine participants' anticipatory anxiety, participants rated how they felt, in the present moment, across six stress-related statements (e.g., "I am worried", "I feel calm"; *1 = Not at all, 4 = Very much*). Research indicates the STAI-6 has good internal consistency $\alpha = .82$ (present study: $\alpha = .88$) and shows similarities in mean score to the full-form STAI (Marteau & Bekker, 1992). Warning studies also use the STAI-6 (e.g., Bridgland et al., 2019). Scores were summed (range: 6-24), with higher scores reflecting greater anticipatory anxiety.

Anticipated Emotion Questionnaire (Appendix G). For our study's purpose, we developed a short questionnaire that examined participants' anticipated emotions (i.e., how they expected to feel) relating to the risk-warning they viewed. We created negative

expectancy items (7 items; e.g., "I expect to feel upset") based on the warned of psychological outcomes in the high risk-warning. We included positive items (3 items; e.g., "I expect to feel happy") to divert attention away from the negative expectancy items.[36] Participants rated the 10 items using a 7-point Likert scale (*0 = I strongly disagree, 3 = I neither agree nor disagree, 6 = I strongly agree*; present study: $\alpha = .78$). Higher scores indicated higher agreement with the described anticipated emotion item.

Balanced Inventory of Desirable Responding Short Form (Hart et al., 2015; Paulhus, 1984; Appendix H). To examine potential demand effects, we measured participants' likelihood to engage in socially desirable responding. Participants rated 16 statements, e.g., "I never cover up my mistakes", on a 7-point Likert scale (*1 = Not true, 4 = Somewhat true, 7 = Very true*), where higher scores indicate a greater tendency to engage in socially desirable responding. As per Stöber et al. (2002), we reverse scored negatively keyed items and summed scores across items (range: 1-112) using a continuous approach. The BIDR-16 has good test re-test reliability (r: .74-.79, < .001) and showed good internal consistency (current study: $\alpha = .88$).

Suspicion Questionnaire. We asked participants several open-text questions to examine what they believed our study's purpose was and whether they believed we expected them to react/respond in a particular way.

Procedure

To enter the study—and to reduce the possibility of bot responding—participants completed a captcha screen and had to score 80% or above on an English proficiency test (see Moeck et al., 2022). We randomly allocated participants to view one of two information forms: one that contained a high risk-warning and another that contained a negligible risk-

[36] Because positive expectancy predictions and subsequent analyses were secondary to our main interest here, we include all positive expectancy results at https://osf.io/ag52n/.

warning. After 30 seconds, participants moved to the next screen where they listened to a brief audio recording of their relevant warning and viewed the consent form, where they chose to consent or not consent.

All participants consented to participate. We planned to ask participants who viewed consent material but decided to *not consent* why they made this decision (in a way that was consistent with our IRB's requirements). However, because all participants consented, as they also did in Experiment 3b, we have no data for this question. Participants completed demographics (i.e., age, self-reported ethnicity, gender, and highest level of education), the STAI-6, Anticipated Emotion Questionnaire, BIDR-16, and the Ten-Item Personality Inventory (administered to align with our cover story; Ehrhart et al., 2003). Participants then encountered a bogus film loading screen and we immediately asked them if, up until this point (in the study), they believed they would view a trauma film (Y/N). We told participants the true purpose of the study and re-consented them (i.e., presented the information and consent form of the true study). Finally, participants completed our suspicion questionnaire and were fully debriefed.

Statistical Overview

We ran frequentist statistical analyses using SPSS 28 (SPSS 29 in Experiment 3b). We also calculated Bayes Factors (BF), using JASP (Version 0.15). For these analyses, we employed Cauchy default priors (0.707) and followed Wetzels et al.'s (2011) guidelines for interpretation. We did not pre-register BF analyses for Experiment 3a but chose to run these analyses to better understand the evidence our data provide, given we found nonsignificant group differences using Null Hypothesis Significance Testing (NHST). Our approach was the same for Experiment 3b.

For our main analyses (i.e., independent samples t-tests), we used corrected significance (p = .007), treating warned of side-effects as "one family". Per pre-registration,

we ran our analyses *without* participants who partially-guessed our hypothesis (i.e., our interest in participant expectancies and/or they thought we expected them to react in a certain way). These analyses did not change the overall pattern of our results (i.e., significance; see https://osf.io/ag52n/ for complete results).

Results and Discussion

Do High-Risk Consent Warnings Change Participant Expectancies?

Anticipatory Anxiety

We first examined whether high risk-warning participants reported more anticipatory anxiety than negligible risk participants (see Table 8.1 for descriptive and inferential statistics). Against predictions, and contrary to prior trigger warning research (Bridgland et al., 2023), negligible risk participants reported significantly more anticipatory anxiety post-warning than high-risk participants; a small-to-medium effect. Our BF analyses indicated substantial evidence in favour of the alternative hypothesis, over the null.

Table 8.1

Descriptive and Inferential Statistics for Warning Condition by Anticipated Emotion and Anticipatory Anxiety One-Way ANOVA Analyses

Anticipated Emotion		High Risk	Negligible Risk	No Warning							
		M (SD)	*M (SD)*	*M (SD)*	*t(df)*	*F(df)*	*p*	*Cohen's d*	*Eta²*	*BF_{01}*	*BF_{10}*
	Experiment										
Distress	3a	1.97 (1.88)	2.16 (1.87)	-	(198) = 0.72	-	.474	0.10	-	5.11 (substantial for null)	-
	3b	2.09 (1.67)	1.19 (1.64)	1.43 (1.76)	-	(2, 297) = 6.61	.001	-	0.05	-	33.97 (very strong for alt.)
Upset	3a	1.93 (1.82)	2.17 (1.82)	-	(198) = 0.93	-	.353	0.13	-	4.33 (substantial for null)	-
	3b	2.05 (1.77)	1.23 (1.64)	1.41 (1.68)	-	(2, 297) = 6.44	.002	-	0.04	-	12.01 (strong evidence for alt.)
Afraid	3a	1.32 (1.65)	1.76 (1.71)	-	(198) = 1.86	-	.065	0.26	-	1.31 (anecdotal for null)	-
	3b	1.45 (1.55)	0.77 (1.35)	1.08 (1.61)	-	(2, 297) = 5.09	.007	-	0.03	-	3.60 (substantial for alt.)
Anxious	3a	2.18 (2.05)	2.49 (1.94)	-	(198) = 1.10	-	.273	0.16	-	3.70 (substantial for null)	-
	3b	2.18 (1.76)	1.22 (1.59)	1.60 (1.83)	-	(2, 297) = 7.82	.001	-	0.05	-	41.01 (very strong for alt.)
Distressing Memories	3a	1.78 (1.88)	2.27 (1.83)	-	(198) = 1.87	-	.063	0.26	-	1.28 (anecdotal for null)	-
	3b	1.57 (1.62)	0.92 (1.52)	1.11 (1.50)	-	(2, 297) = 4.65	.010	-	0.03	-	2.42 (anecdotal for alt.)

Ongoing Distress	3a	1.44 (1.67)	1.79 (1.78)	-	(198) = 1.44	-	.152	0.20	-	2.48 (anecdotal for null)	-
	3b	1.14 (1.41)	0.73 (1.25)	0.80 (1.41)		(2, 297) = 2.60	.076	-	0.02	-	0.38 (anecdotal for null)
Difficulties Sleeping	3a	1.50 (1.82)	1.94 (1.96)	-	(198) = 1.64	-	.102	0.23	-	1.85 (anecdotal for null)	-
	3b	1.07 (1.42)	0.49 (1.17)	0.68 (1.23)		(2, 297) = 5.37	.005	-	0.04	-	4.63 (substantial for alt.)
Happy	3a	2.88 (2.11)	3.18 (1.87)	-	(198) = 1.06	-	.289	0.15	-	3.83 (substantial for null)	-
	3b	2.15 (1.78)	2.52 (1.67)	2.57 (1.72)		(2, 297) = 1.77	.172	-	0.01	-	0.18 (substantial for null)
Energetic	3a	2.95 (1.82)	2.92 (1.75)	-	(198) = 0.12	-	.905	0.02	-	6.46 (substantial for null)	-
	3b	2.02 (1.67)	2.06 (1.75)	2.38 (1.69)		(2, 297) = 1.34	.264	-	0.009	-	0.12 (substantial for null)
Excited	3a	2.55 (1.78)	2.74 (1.73)	-	(198) = 0.77	-	.445	0.11	-	4.94 (substantial for null)	-
	3b	1.86 (1.74)	1.77 (1.71)	2.16 (1.66)		(2, 297) = 1.44	.239	-	0.10	-	0.13 (substantial for null)
STAI-6	3a	9.21 (3.08)	10.73 (4.43)	-	(176.64) = 2.82	-	.005	0.40	-	0.17 (substantial for alt.)	-
	3b	10.16 (3.69)	9.85 (4.13)	10.22 (3.87)		(2, 297) = 0.26	.772	-	0.002	-	0.05 (strong for null)
Neg. Expectancy Composite	3a	1.73 (1.53)	2.08 (1.58)	-	(198) = 1.60	-	.111	0.23	-	16.02 (strong evidence for null)	-

Potentially, negligible risk participants reported more anticipatory anxiety because they received less information about the upcoming participation experience (i.e., what negative side-effects they might experience). Thus, perhaps their experience felt more uncertain or unpredictable than participants in the high risk-warning condition. Indeed, some prior research suggests that when future negative events are less certain or predictable, anxiety increases due to people's inaccurate expectancies about a future threat (Anderson et al., 2019; Grupe & Nitschke, 2013). However, closer inspection of the means and scale anchors showed both conditions were somewhere between "not at all" and "somewhat" anxious. Therefore, this group difference likely holds little practical significance.

Anticipated Negative Emotion

Next, we examined whether participants exposed to the high risk-warning anticipated feeling more negative (e.g., distressed) than participants exposed to the negligible risk-warning. Our predictions were unsubstantiated: all analyses showed a nonsignificant difference between warning conditions on anticipated emotion outcomes (see Table 8.1). Our BF analyses confirmed anecdotal to substantial evidence in favour of the null hypothesis (i.e., no group differences), relative to the alternative.

Together, these findings indicate that, regardless of the warning participants encountered, they did not expect to experience negative emotions while participating in a psychological trauma-related study. Our anticipated negative emotion results deviate from prior trigger warning studies that have found warned participants (versus unwarned) expect a video (Sanson et al., 2019) or photographs (Bridgland et al., 2019) to be more negative. We also found, overall, *low* rates of anticipated negative emotion. On average, participants indicated being somewhere between *disagreement* and *indifference* in relation to expecting to experience the warned of psychological side-effects (e.g., distress), irrespective of warning type.

One explanation for our findings is that our risk-warnings flagged institutional support to participants, the opposite to institutional betrayal (i.e., when an institution inadequately responds to a person's traumatic experience(s) and their needs relating to such experience(s); Smith & Freyd, 2014). Indeed, one trigger warning study found institutional betrayal explained more variance in participants' support for trigger warning use than other psychological factors like PTS symptoms (Bruce & Roberts, 2020), meaning that when people receive trigger warnings, they feel supported by an institution. Here, our warnings were clearly IRB-approved *and* accompanied with an audio clip emphasising IRB involvement.

Another possibility is that participants engaged in emotion management strategies (e.g., Gross et al., 2006) that neutralised their reported expectancies. Indeed, seventeen participants (high-risk: 8, negligible risk: 9) revealed in the suspicion survey "…[using] [warning] information to mentally prepare for what came next", "…preparing [themselves] and [their] frame of mind to minimise the potential impact of negative content" or comparing their projected participation experience to other stressful and/traumatic events they have navigated in their life (e.g., working in trauma-focused settings, witnessing traumatic events). Perhaps then—as a form of participation preparation—people's reported expectancies were consistent with mentally preparing or engaging in emotion management. However, prior research suggests warnings do not help people emotionally prepare to encounter potentially distressing content (Bridgland et al., 2022; Bridgland et al., 2023). Therefore, maybe people erroneously *felt* they were subjectively forearmed—given the risk-warning—even though they objectively were not (e.g., they were not necessarily using an effective emotion regulation strategy; Bridgland et al., 2022).

Socially Desirable Responding

To determine to what extent demand effects could account for our results, we examined whether participants' socially desirable responding scores moderated the relationship/s between condition and anticipated emotion/anticipatory anxiety. We ran several moderated regressions (model 1) using the PROCESS macro on SPSS V28 (Hayes, 2022). We entered condition as the independent variable, socially desirable responding as the moderator, and anticipated emotions and anticipatory anxiety as the dependent variables. We found no evidence that socially desirable responding moderated the relationship between condition and anticipated emotions and anticipatory anxiety, *p*s: .108 - .956 (see full results at https://osf.io/ag52n/).

Because some participants reported—contrary to our overall findings—that they were anxious and/or worried during participation (i.e., in their suspicion survey responses), we ran exploratory correlational analyses on participants' BIDR-16 scores; these analyses were not pre-registered (see complete results at https://osf.io/ag52n/). BIDR-16 scores significantly *negatively correlated* with all negative expectancy items (e.g., "I expect to feel distressed"), *r*s: -.435 to -.340, *p*s: < .001 and anticipatory anxiety $r = -.42$, $p < .001$. Thus, as socially desirable responding scores decreased, negative expectancy item scores increased.

This pattern of results suggests that demand effects may have influenced our findings: perhaps participants *downplayed* their anticipated negative emotions. Or, perhaps even if the warning caused participants to anticipate negative emotions, participants responded in ways consistent with their decision to participate (e.g., tolerating participation). In other words, participants potentially resolved dissonance-related feelings about participation (Festinger, 1957). Indeed, several responses to our suspicion survey supported this possibility: participants (high-risk = 6; negligible risk = 4) reported considering whether they could

tolerate warned of risks (i.e., “I did worry that the video was going to upset me…”, “I wasn’t especially looking forward to viewing something harsh…”).

Summary

Overall, we found no evidence that consent risk-warnings changed participant expectancies for a psychological trauma-related study. Participants generally disagreed that the high risk-warning caused them to anticipate experiencing negative psychological side-effects (e.g., distress). And surprisingly, negligible risk participants reported higher anticipatory anxiety than high-risk participants. These findings are inconsistent with related trigger warning findings (Bridgland et al., 2023), suggesting that consent risk-warnings may be unique in their effects. However, methodologically speaking, our experiment differed to prior trigger warning experiment methodologies in two key ways (Bridgland et al., 2023).

First, prior trigger warning studies measuring expectancies found participants in a *trigger warning condition* expected the content to be more negative than participants in a *no warning* condition (Bridgland et al., 2019; Sanson et al., 2019). Yet here, we compared *two* warning conditions. Some prior warning research suggests that providing people with any warning—like our neutral negligible risk-warning—can influence their responses (versus no warning; e.g., Bridgland et al., 2019; Faasse, Huynh et al., 2019). Perhaps then participants exposed to a high risk-warning would have higher negative expectancy ratings—including higher anticipatory anxiety—compared to participants who are exposed to no warning. We addressed this possibility in Experiment 3b.

Second, prior trigger warning research measuring expectancies also measures participant reactions pre- and post-warning (Bridgland et al., 2019; Sanson et al., 2019). Here we only collected participant responses post-warning. Perhaps people exposed to a high risk-warning would report significantly higher negative expectancy ratings—including higher

anticipatory anxiety—if we measured the *change* from pre-to-post, relative to negligible risk or no warning participants. We rectified this measurement limitation in Experiment 3b.

Moreover, when we piloted the methodological changes described above—prior to running Experiment 3b—some participants reported difficulty in responding to our Anticipated Emotion measure, such as not knowing what *timeframe* to base their "I expect to feel" judgments on (e.g., now, or in the future). Perhaps participants in Experiment 3a based their ratings on different timeframe references (e.g., some participants framed judgments based on 5 minutes time, at the end of the study, or 1 week after the study), making our findings difficult to interpret. We addressed this measurement issue in Experiment 3b.

Given our findings in Experiment 3a, and following extensive pilot testing, we made several methodological changes in Experiment 3b to better address whether consent risk-warnings change participant expectancies for a psychological trauma-related study. Specifically, we: added a no warning condition, included pre-warning expectancy measures, and altered the Anticipated Emotion measure framing.

We propose competing hypotheses for Experiment 3b. On the one hand, in line with the idea of expectancy effects (Kirsch, 1985), existing trigger warning literature (Bridgland et al., 2023), and our original hypotheses from Experiment 3a, consent risk-warning type may alter participant expectancies regarding their psychological trauma research experience. According to this line of reasoning, we would expect: participants exposed to the high risk-warning will anticipate feeling more distressed, upset, anxious, and afraid; anticipate more ongoing psychological distress, difficulties sleeping, and distressing memories (i.e., higher mean scores) after participating in the study, than participants who view the negligible risk or no warning. Additionally, based on our pre-warning expectancy measure addition (i.e., measuring responses to risk-warnings over time), we would also predict that warning condition will interact with time, where time has a larger effect for participants in the high-

risk condition—that is, participants would have greater increases in their mean scores on negative expectancy items (e.g., distress, upset, anxiety)—pre-to-post-warning than participants in the negligible risk or no warning conditions. Regarding anticipatory anxiety, participants exposed to the high risk-warning will report higher anticipated anxiety than participants exposed to the negligible risk or no warning. We further expect warning condition to interact with time, where participants in the high-risk condition will report greater change in mean anticipatory anxiety pre-to-post-warning than participants in the negligible risk or no warning conditions.

Alternatively, recall that we could not rule out the possibility that participants engaged in emotion-regulation strategies in response to our warnings (e.g., mentally preparing themselves to complete our trauma-described study) or that they adjusted how they felt to align with successful study completion (i.e., to alleviate cognitive dissonance). If true, we would expect no difference in mean agreement ratings for negative expectancy items between warning conditions or over time. Regarding anticipatory anxiety, potentially participants given less information (i.e., negligible risk and no warning conditions) about their potential reaction to the upcoming participation experience may perceive that experience as more uncertain and unpredictable than participants given more information (i.e., high-risk condition). Here then, we would expect participants exposed to the negligible risk-warning (and no warning) will report higher anticipatory anxiety than participants exposed to the high risk-warning. We further predict that warning condition may interact with time, such that time will have a larger effect for participants in the negligible risk (and no warning) conditions (i.e., greater mean change in anticipatory anxiety pre-to-post-warning) than participants in the high-risk condition.

Experiment 3b

Method

Participants

Per our pre-registration, we aimed to collect 300 participants. We based this decision on several factors. First, for our primary analysis (i.e., repeated measures, within-between interaction ANOVA), an *a priori* analysis using G*Power (input: $\alpha = .05$, 80% power and small-to-medium effect size, $f = 0.20$) recommended $N = 123$. For additional analyses of interest (i.e., post-hoc tests, one-way ANOVAs), G*Power recommended $N = 200$ (input: $\alpha = .05$, 80% power and small-to-medium effect size, $d = 0.40$; see also Brysbaert, 2019) and $N = 246$ (input: $\alpha = .05$, 80% power and small-to-medium effect size, $f = 0.20$), respectively. Further, our sample size fit within our resource capacity (Lakens, 2022), while meaning we were well-positioned to detect small-to-medium effects for our analyses. Our decision to power for small-to-medium (and larger) effects was the same as in Experiment 3a.

We collected 327 US-based participants using MTurk. We excluded 20 participants for not believing they would view a traumatic film and seven participants for guessing our study's aim. Our final sample comprised 300 participants who were 51.7% women (men: 45.3%, non-binary: 2.3%, prefer not to say: 0.7%), aged 20 – 79 ($M = 42.43$, $SD = 11.72$). Of our sample, 69.7% self-identified ethnicity as white/Caucasian (Mixed: 8%, black/African American: 7.7%, Asian: 3.7%, Hispanic: 2.7%, Latino: 0.7%, Other [e.g., "prefer not to say"]: 0.7%, Vietnamese: 0.3%, African: 0.3%, Indian: 0.3%, Middle Eastern: 0.3%, Chinese: 0.3%; 5.3% also self-identified via nationality, e.g., "American"). Just under half (41%) our sample's highest education level was a bachelor's degree, followed by high school/equivalent (24.7%), associate degree/diploma (20%), master's degree (11.7%), doctoral studies (2.3%), and primary school (0.3%). Participants were compensated US $1.20.

Materials

Most materials remained the same in Experiment 3b, but we added a timeframe reference to the Anticipated Emotion Questionnaire (i.e., "We would like you to imagine how you will feel *after participating in the study* you signed up for"). We also added a no warning condition. Participants in this condition viewed the same information sheet and consent form as our other conditions, however, there was no information regarding potential participation risks/side-effects.

Procedure

Experiment 3b's procedure mirrored Experiment 3a, with the following exceptions. Upon entering the study, participants completed screening measures *prior to* viewing the information sheet and consent form. These "screening measures"—Anticipated Emotion Questionnaire and STAI-6—formed our pre-warning expectancy measures. Next, participants were randomly allocated to view the high risk-warning, negligible risk-warning or no warning consent form. Participants who viewed the high-risk and negligible risk-warnings listened to their associated warning audio clips; participants in the no warning condition did not listen to an audio clip.

Statistical Overview

In line with best practice, we applied corrected significance ($p < .005$) based on familywise corrections for 10 anticipated emotion items and applied Bonferroni corrections to post-hoc tests. However, see https://osf.io/ag52n/ for uncorrected analyses where the pattern of results somewhat differs. For our ANOVA analyses, data checks indicted all dependent variables violated the assumption of normality (Shapiro-Wilk < .001); visual inspection of histograms showed strong positive skew. Transformations did not improve skew, thus, for ease of interpretation, we report untransformed data here. Despite random allocation, we also detected baseline differences by condition on two anticipated emotion

items (distress and anxious: *p*s: = .030 - .041). Thus, for these variables, we deviated from our pre-registered plan and instead used ANCOVA, with baseline scores as the covariate. We note that for ANCOVA, the assumption of linearity was unmet, but since transformations did not address the issue, we proceeded with analyses.

We repeated our main pre-registered analyses after removing participants who partially-guessed our hypothesis. Where the results of these repeated analyses changed (i.e., significance), we report alongside the corresponding original result below. While we pre-registered calculating a post-warning negative expectancy composite score to align with Sanson et al.'s (2019) negative expectancy composite score, for comparison's sake, we chose to additionally calculate a pre-warning negative expectancy composite. Further, per our pre-registration, we collapsed the two warning conditions to compare against our no warning condition. However, because these analyses were exploratory and we obtained nonsignificant results, we report them in full at https://osf.io/ag52n/.

Results and Discussion

Do our Results From Experiment 3a Replicate?

We first ran several one-way ANOVAs—with Bonferroni correction—on *post-warning* anticipated emotion scores (see Tables 8.1 and 8.2).

Table 8.2

Post-Hoc Results for Mixed Model ANOVA, ANCOVA, and One-Way ANOVA Analyses

Variable			Mixed-Model ANOVA/ANCOVA		One-Way ANOVA	
	Comparison		*p*	*Cohen's d*	*p*	*Cohen's d*
STAI-6	High-Risk	Negligible Risk	1.00	0.08	1.00	0.08
		No Warning	1.00	0.05	1.00	0.02
	Negligible Risk	No Warning	1.00	0.13	1.00	0.10
Distress*	High-Risk	Negligible Risk	.002	0.49	.001	0.53
		No Warning	.001	0.54	.018	0.39
	Negligible Risk	No Warning	1.00	0.05	.948	0.14
Upset	High-Risk	Negligible Risk	.020	0.34	.002	0.48
		No Warning	.884	0.13	.024	0.38
	Negligible Risk	No Warning	.282	0.21	1.00	0.12
Afraid	High-Risk	Negligible Risk	.056	0.29	.005	0.45
		No Warning	1.00	0.09	.252	0.25
	Negligible Risk	No Warning	.307	0.20	.442	0.21
Anxious*	High-Risk	Negligible Risk	.001	0.56	.001	0.56
		No Warning	.001	0.56	.055	0.34
	Negligible Risk	No Warning	1.00	0.005	.364	0.22
Distressing Memories	High-Risk	Negligible Risk	.055	0.29	.010	0.42
		No Warning	1.00	0.10	.110	0.30
	Negligible Risk	No Warning	.343	0.20	1.00	0.12

Ongoing Distress	High-Risk	Negligible Risk	.338	0.20	.102	0.30
		No Warning	1.00	0.08	.235	0.25
	Negligible Risk	No Warning	1.00	0.12	1.00	0.05
Difficulties Sleeping	High-Risk	Negligible Risk	.076	0.29	.004	0.46
		No Warning	.540	0.17	.094	0.31
	Negligible Risk	No Warning	1.00	0.12	.879	0.15
Happy	High-Risk	Negligible Risk	1.00	0.11	.390	0.22
		No Warning	1.00	0.04	.258	0.24
	Negligible Risk	No Warning	1.00	0.07	1.00	0.03
Excited	High-Risk	Negligible Risk	1.00	0.07	1.00	0.05
		No Warning	.912	0.13	.642	0.18
	Negligible Risk	No Warning	.331	0.21	.319	0.23
Energetic	High-Risk	Negligible Risk	1.00	0.10	1.00	0.02
		No Warning	1.00	0.07	.409	0.21
	Negligible Risk	No Warning	.594	0.17	.556	0.19
Pre-Warning Negative Expectancy Composite	High-Risk	Negligible Risk	-	-	.737	0.17
		No Warning	-	-	.831	0.83
	Negligible Risk	No Warning	-	-	.076	0.08
Post-Warning Negative Expectancy Composite	High-Risk	Negligible Risk	-	-	.001	0.54
		No Warning	-	-	.027	0.37
	Negligible Risk	No Warning	-	-	.703	0.17
Pre-Warning Positive Expectancy Composite	High-Risk	Negligible Risk	-	-	1.00	0.12

		No Warning	-	-	1.00	0.06
	Negligible Risk	No Warning	-	-	1.00	0.06
Post-Warning Positive Expectancy Composite	High-Risk	Negligible Risk	-	-	1.00	0.07
		No Warning	-	-	.278	0.24
	Negligible Risk	No Warning	-	-	.709	0.17

Note. * Denotes ANCOVA results

Here, we failed to replicate several findings from Experiment 3a. Where we previously found no significant difference between warning conditions on negative anticipated emotion, we found anticipated distress, upset, anxiety, and difficulties sleeping scores significantly differed by warning condition. High-risk participants reported significantly greater anticipated distress and upset, compared to all other warning conditions; and greater anticipated anxiety and difficulties sleeping than negligible risk participants. These comparisons were of small-to-medium effect size. All other post-hoc comparisons were nonsignificant (see Table 8.2).

Overall, these results suggest high-risk consent warnings change participants' negative expectancies, compared to receiving a negligible risk or no warning. There are several reasons why these results are different to Experiment 3a, including random variation, differences in assumption violations (Amrhein et al., 2019), and our small—potentially significant—methodological changes between experiments (e.g., asking participant expectancies at two time points versus one time point). Interestingly though, when we compare means across our experiments, we see that *negligible risk* participants reported *lower* anticipated emotion; for instance, for the negligible risk condition, anticipated distress post-warning in Experiment 3b was $M = 1.19$, compared to Experiment 3a where $M = 2.16$. For the high risk-warning condition, anticipated distress was $M = 2.09$ and $M = 1.97$, in Experiments 3b and 3a, respectively. Hence, negligible risk participant responses seem to drive the change in Experiment 3b results. Methodological differences between Experiments 3a and 3b might explain why participants in the negligible risk condition reported, on average, lower anticipated emotion. For instance, although negligible risk-warning participants were not warned about side-effects in Experiment 3b, they were still exposed to the idea of side-effects via our baseline measures (e.g., "I expect to experience distress"). This information may have decreased people's uncertainty.

Anticipatory Anxiety

Our anticipatory anxiety results from Experiment 3a *did not* replicate. Instead, we found participants reported similar anticipatory anxiety regardless of warning condition (i.e., non-significant). BF analyses confirmed strong evidence in favour of the null hypothesis, relative to the null. Our results therefore do not fit with the idea that negligible risk participants reported greater anticipatory anxiety due to having less information (i.e., about potential side-effects) or experiencing greater uncertainty, than high-risk participants. Moreover, across both experiments, our findings ran counter to prior trigger warning literature (Bridgland et al., 2023). Therefore, risk-warnings do not seem to increase participants' anticipatory anxiety.

Socially Desirable Responding

For exploratory purposes, we again ran correlation analyses on participants' socially desirable responding and post-warning scores (see https://osf.io/ag52n/ for results in full). Similar to Experiment 3a, participant's BIDR-16 scores were significantly negatively correlated with almost all negative expectancy items (excluding difficulties sleeping, p = .063), rs: -.11 to -.19, ps: .001 to .049 and anticipatory anxiety, r = -.37, p < .001. Therefore, as participant's socially desirable responding scores decreased, negative anticipated emotion and anticipatory anxiety scores increased. Although we acknowledge we cannot draw causal inferences from these findings, our results may indicate participants self-reported their expectancies in ways consistent with resolving feelings of cognitive dissonance or socially desirable responding.

Do High-Risk Consent Risk-Warnings Change Participant Expectancies Over Time?

We conducted 3 (condition: high-risk, negligible risk, no warning) x 2 (pre-warning, post-warning) mixed model ANOVA analyses on anticipated and anticipatory emotion items (see Table 8.3).

Table 8.3

Descriptive, Inferential, and Bayes Factor Statistics for Mixed-Model ANOVA Results

	High Risk		Negligible Risk		No Warning							
	Baseline *M (SD)*	Post-Warning *M (SD)*	Baseline *M (SD)*	Post-Warning *M (SD)*	Baseline *M (SD)*	Post-Warning *M (SD)*	*F(df)*	*p*	*Partial eta squared*	BF_{10}	Condition Main Effect *F(df), p, partial eta squared*	Time Main Effect *F(df), p, partial eta squared*
STAI-6	9.76 (3.63)	10.16 (3.69)	9.42 (3.94)	9.85 (4.13)	10.05 (3.95)	10.22 (3.87)	(2, 297) = 0.60	.550	0.004	0.08 (strong evidence for null)	(2, 297) = 0.46, .635, 0.003	(1, 297) = 9.85, .002, 0.03
Distress*	0.98 (1.44)	2.09 (1.67)	0.68 (1.19)	1.19 (1.64)	1.18 (1.55)	1.43 (1.76)	(2, 296) = 8.83	.001	0.06	4.31e+17 (substantial for alt.)	-	-
Upset	1.00 (1.36)	2.05 (1.77)	0.78 (1.30)	1.23 (1.64)	1.24 (1.38)	1.41 (1.68)	(2, 297) = 9.42	.001	0.06	178.11 (decisive for alt.)	(2, 297) = 3.79, .024, 0.03	(1, 297) = 43.30, .001, 0.13
Afraid	0.69 (1.13)	1.45 (1.55)	0.59 (1.10)	0.77 (1.35)	0.82 (1.17)	1.08 (1.61)	(2, 297) = 5.84	.003	0.04	6.77 (substantial for alt.)	(2, 297) = 2.94, .055, 0.02	(1, 297) = 28.39, .001, 0.09
Anxious*	1.15 (1.45)	2.18 (1.76)	0.91 (1.35)	1.22 (1.59)	1.46 (1.57)	1.60 (1.83)	(2, 296) = 10.42	.001	0.07	∞ (decisive for alt.)	-	-
Distressing Memories	0.88 (1.31)	1.57 (1.62)	0.70 (1.23)	0.91 (1.53)	1.06 (1.38)	1.11 (1.50)	(2, 296) = 5.71	.004	0.04	6.36 (substantial for alt.)	(2, 296) = 2.91, .056, 0.02	(1, 296) = 15.57, .001, 0.05
Ongoing Distress	0.68 (1.25)	1.14 (1.41)	0.58 (1.11)	0.73 (1.25)	0.82 (1.36)	0.80 (1.41)	(2, 297) = 3.58	.029	0.02	0.38 (anecdotal for null)	(2, 297) = 1.29, .278, 0.009	(1, 297) = 7.01, .009, 0.02
Difficulties Sleeping	0.65 (1.23)	1.07 (1.42)	0.51 (1.12)	0.49 (1.17)	0.61 (1.25)	0.68 (1.23)	(2, 297) = 5.27	.006	0.03	4.27 (substantial for alt.)	(2, 297) = 2.56, .079, 0.02	(1, 297) = 7.17, .008, 0.02

Happy	3.10 (1.69)	2.15 (1.78)	3.11 (1.62)	2.52 (1.67)	2.81 (1.62)	2.57 (1.72)	(2, 297) = 5.70	.004	0.04	6.47 (substantial for alt.)	(2, 297) = 0.41, .665, 0.003	(1, 297) = 47.73, .001, 0.14
Excited	2.31 (1.72)	1.86 (1.74)	2.15 (1.63)	1.77 (1.71)	2.46 (1.66)	2.16 (1.66)	(2, 297) = 0.31	.736	0.002	0.05 (strong evidence for null)	(2, 297) = 1.32, .296, 0.009	(1, 297) = 23.28, .001, 0.07
Energetic	2.62 (1.82)	2.02 (1.67)	2.25 (1.67)	2.06 (1.75)	2.51 (1.67)	2.38 (1.69)	(2, 297) = 4.04	.019	0.03	1.33 (anecdotal for alt.)	(2, 297) = 0.84, .434, 0.006	(1, 297) = 17.43, .001, 0.06
Pre-Warning Negative Expectancy Composite	0.86 (1.09)	-	0.68 (1.03)	-	1.02 (0.86)	-	(2, 296) = 2.53	.081	0.02	0.36 (anecdotal for null)	-	-
Post-Warning Negative Expectancy Composite	-	1.65 (1.35)	-	0.94 (1.26)	-	1.15 (1.35)	(2, 297) = 7.64	.001	0.05	34.86 (very strong for alt.)	-	-
Pre-Warning Positive Expectancy Composite	2.67 (1.54)	-	2.50 (1.36)	-	2.59 (1.49)	-	(2, 297) = 0.35	.705	0.002	0.05 (strong evidence for null)	-	-
Post-Warning Positive Expectancy Composite	-	2.01 (1.52)	-	2.11 (1.50)	-	2.37 (1.51)	(2, 297) = 1.50	.225	0.01	0.14 (substantial for null)	-	-

Note. * Denotes anticipated emotion items analysed using ANCOVA.

Anticipatory Anxiety

Numerically, mean anticipatory anxiety increased from pre-to-post warning in the high-risk condition, but overall means (~ 10) were similar across warning conditions. Based on scale anchors, participants reported being somewhere between "not at all" to "somewhat" anxious. Despite expectations, participants did not experience a statistically significant increase in anticipatory anxiety pre-to-post warning; a nonsignificant interaction of small effect size. Moreover, our BF analysis showed strong evidence in favour of the null hypothesis, over the alternative. While our small effect size mirrored prior trigger warning effect sizes (Bridgland et al., 2023), our overall finding was inconsistent with the usual finding that participants experience a small increase in anticipatory anxiety after viewing a trigger warning (versus no warning; Bridgland et al., 2023). Thus, participants appear to experience low-level anticipatory anxiety, *regardless* of consent risk-warning type. Similar to acclimation periods used in experimental stress research (e.g., Labuschagne et al., 2019), such low-level anxiety may reflect participants' adjustment to study demands as they begin participation.

Anticipated Emotion: Negative

We found evidence for our predicted condition by time interaction for several items: anticipated upset, afraid, distressing memory (ANOVA), and distress and anxiety (ANCOVA after controlling for baseline differences) items (see Table 8.2 and 8.3). High risk-warning participants reported significantly greater anticipated upset than negligible risk participants; no other post-hoc comparisons reached significance (including afraid and distressing memory comparisons; see Table 8.2). Our lack of statistically significant post-hoc comparisons likely reflect our conservative correction use. We note that after removing participants who partially-guessed our hypothesis, our interaction for the distressing memory item no longer met corrected significance. BF analyses showed substantial and decisive evidence,

respectively, in favour of the alternative hypothesis (i.e., that the warning conditions differ in anticipated emotion) over the null.

For the remaining anticipated negative emotions (i.e., ongoing distress, difficulties sleeping), the time by condition interactions did not meet corrected significance—and these effects were small. For anticipated ongoing distress, our BF analyses indicated anecdotal evidence in favour of the null, but for anticipated difficulties sleeping, we found substantial evidence in favour of the alternative hypothesis, relative to the null. Post-hoc comparisons, while nonsignificant for both anticipated emotions, showed small differences between the high-risk and negligible risk-warning conditions. Removing partial hypothesis guess participants changed the interaction term for anticipated sleep difficulties to meet corrected significance, but post-hoc comparisons remained nonsignificant.

Together, our findings indicate high risk-warnings *might* change negative expectancies for psychological side-effects. These findings hold true for short-term anticipated emotions (e.g., distress, upset, anxiety), but not long-term anticipated emotions and/or outcomes (e.g., ongoing distress, difficulties sleeping). Although we found limited evidence that high risk-warnings *change* negative expectancies, closer inspection of the high-risk condition means showed they were still *low* (means ~ 1.45 to 2.18, where *0 = I strongly disagree and 3 = I neither agree nor disagree*), indicating high-risk participants were somewhere between *disagreeing* and feeling *indifferent* toward anticipating warned of side-effects (e.g., distress) after participation. Thus, although the high risk-warning significantly increased participants' anticipated negative emotion, the warning does not push people beyond indifference toward anticipating warned of psychological side-effects.

We additionally calculated pre- and post-warning negative expectancy composite scores (by adding all negative expectancy items and dividing by 7). Although there was no difference on pre-warning negative expectancy scores, our one-way ANOVA showed a

significant small-to-medium difference between warning conditions on post-warning negative expectancy scores. Our BF indicated very strong evidence in favour of the alternative hypothesis, over the null. High risk-warning participants had significantly greater post-warning negative expectancy scores than participants in the other warning conditions; of small-to-medium effect size. Although these results align with prior trigger warning expectancy findings (e.g., trauma film; Bridgland et al., 2019; Sanson et al., 2019), we again note that the high-risk condition's overall post-warning negative expectancy mean was still relatively low on our expectancy measure scale; that is, 1.65, where *0 = I strongly disagree, 3 = I neither agree nor disagree, 6 = I strongly agree*.

General Discussion

Here, we examined whether providing participants with different consent risk-warnings for a psychological trauma-related study changed their expectancies for warned of psychological side-effects. In Experiment 3b, when we measured participant expectancies pre- and post-warning, and asked them to evaluate the experience as occurring after the study (i.e., judgment timeframe), we found some evidence for this risk-warning possibility: participants who encountered the high-risk consent warning reported higher (i.e., more negative) expectancies for potential psychological side-effects than negligible risk or no warning participants. However, in Experiment 3a, when participant expectancies were only evaluated post-warning and without a judgment timeframe (i.e., to base anticipated emotion judgments on), participant expectancies did not differ between conditions. Additionally, across both experiments, we found that *irrespective* of risk-warning type, participants generally *disagreed* that they expected to experience negative psychological side-effects associated with participation.

The good news for IRBs and researchers is that people may not develop strong negative expectancies when exposed to risk-warnings at consent while participating in online

trauma-related research. Moreover, since this first step in the chain of traditional nocebo effects was not realised (e.g., Rooney et al., 2023), one interpretation of our data is that consent risk-warnings do not lead participants to experience nocebo effects. Following this line of thinking, consent risk-warnings in their current form are probably not causing negative outcomes for participants, meaning IRBs and researchers are not violating *beneficence* (i.e., cause no harm; NHMRC, 2023).

But the bad news is that our findings indicate consent risk-warnings are not working as intended. If they were, in this study, we should have found *most* participants forming *some* expectancies about warned of side-effects, causing a few participants to *not consent* to participate. Here, over 500 participants consented to participate regardless of the warning encountered. This finding is consistent with prior research indicating people tend to *approach,* rather than avoid, potentially negative content (Bridgland et al., 2023; Kimble et al., 2021). Further, our findings indicated that participants who engaged in socially desirable responding reported *lower* anticipated negative emotions—rather than the higher negative emotions that would be in line with adopting the suggestion and/or demand effects. This finding is in fact the *opposite* of what we would expect to see if participants were adopting researcher suggestions from consent risk-warnings. This finding is also concerning because it may suggest that participants who are susceptible to social desirability attempt to appease researchers by downplaying their anticipated distress. That is, since participants have to agree in the consent information that they will not participate if they anticipate feeling distressed, downplaying negative emotion aligns with their decision to consent and shows researchers that they are in fact okay to participate. Thus, our findings call into question how useful consent risk-warnings are for participants, beyond protecting the institution (Loftus & Fries, 2008).

One possibility why consent risk-warnings—in a psychological trauma research context—may not work as intended is their presence in everyday life; warnings are prolific (e.g., film classifications, trigger/content warnings; Bridgland et al., 2023). Therefore, people may be desensitised to their intended effect. A second possibility relates to prior experience. Our samples likely comprised people who had previously completed psychological research studies and perceived themselves as, on average, *very experienced* (Stirling & Takarangi, 2024), meaning prior experience with other informed consent risk-warnings and/or participation in psychological trauma research. Potentially, participants' expectancies for psychological side-effects reflected their considerable experience with prior risk-warnings/reactions to participation. For instance, if participants do not adhere to risk-warnings in other studies and do not experience negative side-effects, they would expect the same here.

Regarding consent risk-warnings then, our findings leave us with two possible interpretations. First, risk-warnings may not adequately inform participants of the potential risks associated with participating in a psychological trauma study. This is despite their preferred use by IRBs to help mitigate risk and uphold informed consent principles (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006). Second, risk-warnings could set participants up for expectancy violations (e.g., Rief & Petrie, 2016). Prior research suggests people experience difficulties when predicting their future emotional reactions (e.g., Wilson & Gilbert, 2003). Potentially then, if participants were not expecting to experience warned of side-effects, they may be surprised if they find participation is more distressing than anticipated (e.g., that the analogue trauma film is more graphic). Hence, participants may experience *unexpected negative reactions*; such reactions have been previously implicated in research examining how people respond to participation in psychological trauma-related research (e.g., Ruzek & Zatzick, 2000). Moreover, this expectancy violation explanation may

be one reason we would observe the final step in our chain—nocebo effects—even *without* the first step, negative expectancies. In other words, participants might not *expect* to feel distressed, but after exposure to the warned of participation experience, do feel distressed. Indeed, it could be this mismatch between expectation and experience that causes participants to feel worse (e.g., more distressed; see also Affective Expectation Model by Wilson et al., 1989).

Participants' overall lack of negative expectancies and anticipatory anxiety regarding side-effects, in the current study, diverged from prior trigger warning research (e.g., Bridgland et al., 2019; Sanson et al., 2019). There are several potential reasons for this discrepancy. One explanation relates to the warnings themselves. The warnings used in trigger warning studies are mostly directed at *content* (Bridgland et al., 2019; Sanson et al., 2019), whereas here, our high risk-warning was directed at psychological *side-effects*. Further, Sanson et al. did not find changes to negative expectancies when psychological outcomes were measured individually (e.g., distress, upset). But when these negative outcomes were combined via a composite score, Sanson et al. found participants expected the photographs to be more negative; we found a similar pattern of results in Experiment 3b with our negative expectancy composite score. Our findings may therefore indicate that negative expectancies for research participation are cumulative—or considered by participants globally—rather than singularly.

A second, and related, explanation for our discrepant findings is related to the term "trigger warning". Previous research finds that the term "trigger warning" alone (e.g., "…Researchers have been asked to give a trigger warning for the clip") is enough to increase participant's anticipatory anxiety (versus no warning; Bruce et al., 2023). Thus, since this term was absent from our risk-warning, perhaps it is cultural expectations (e.g., usually attached to graphic/disturbing content online) about the term "trigger warning" that causes

these affective changes in participants, rather than the warning of potential psychological side-effects (i.e., negative suggestion) during consent.

The third explanation relates to the purpose of warnings: trigger warnings aim to protect vulnerable people (i.e., from prior distressing and/or negative experiences) by helping them prepare and/or avoid potentially negative content (Bridgland et al., 2023). But consent risk-warnings aim to inform participants of potential psychological side-effects they may experience because of participation (Stirling et al., 2023). Perhaps this difference in purpose—i.e., protection from reaction to content versus informing people of possible side-effects—explains our discrepant findings. Taken together, both the *purpose* and *context* of these warnings seem to matter.

Interestingly, a subset of our participants reported engaging in emotion-management strategies; a positive sign where participation is concerned. This engagement fits with Rief and Petrie's (2016) Violex Model, whereby people may deploy "data-orientated immunisation techniques"—like reframing the situation—to overcome an expectancy violation. Here, some participants may have believed that either they would not experience warned of side-effects or that they should avoid experiencing them to successfully participate in the study. They therefore may have deployed emotion-management strategies to maintain this expectancy (Rief & Petrie, 2016). However, this explanation suggests that any potential effects between warning groups were washed out because not everyone adopted the expectancy set up by the risk-warning. Future research should directly measure these strategies to determine how participants respond during the consent process.

Our study was limited in several ways. We did not measure PTSD symptomology and/or prior trauma exposure history because of our study design (i.e., we only had people enter our study believing they would participate in it), thus our findings could differ for these

subpopulations. However, we suspect, based on prior related research, our findings would remain similar (e.g., Bridgland et al., 2023).

Also, due to our study design, participants did not experience nocebo administration (i.e., viewing the trauma film and/or completing participation). From a retrospective priming perspective (Minton et al., 2017), participants potentially needed exposure to the risk-warning (i.e., prime) *and* participation experience (i.e., target) first, to use the warning to make sense of their experience (e.g., as distressing). Indeed, the present study was short, approximately 12 minutes, comprising screening and informed consent procedures.

Our risk-warnings were inherently limited. The warning length varied between conditions and may have influenced participants' curiosity (e.g. providing people with more information may have decreased their uncertainty, leading to lower negative expectancies); or feelings of importance (e.g., participants who received more information may have judged it as more important or profound, influencing their negative expectancies). Specific to Experiment 3b, participants may have been primed to notice and/or self-report more negative reactions by the repeated anticipated emotion and anticipatory anxiety measurement points, particularly within the high risk-warning condition. Indeed, when we removed partial hypothesis guess participants, several of our results changed in that experiment.

Further, to ensure participants processed our risk-warning—since participants do not always read and/or comprehend consent information (e.g., Douglas et al., 2021)—we presented an audio recording containing the risk-warning. Perhaps the AI voice affected participant's interpretation of the warning (e.g., the voice may have made participants feel uncomfortable or uneasy), regardless of condition. However, we tested this possibility in a small pilot (see Supplementary Files at the end of this Chapter or https://osf.io/ag52n/) and participants reported numerically greater expected distress scores when reading versus hearing the warning. Hence, if anything, the AI voice seemed to numerically lower negative

expectancy scores, possibly making people feel comforted because we drew additional attention to informing people about the risks (e.g., making them feel cared for). Finally, self-selection may have influenced our findings (e.g., people with greater emotional resilience might consent to participate in psychological trauma research because they feel they can cope with it).

In sum, our experiments represent the first step of the nocebo effect chain—i.e., expectancies—in examining whether consent risk-warnings in psychological trauma-related research cause adverse outcomes for participants. Here, risk-warnings did not cause *strong* negative expectancies for warned of psychological side-effects. While our hypotheses were unsubstantiated, our findings raised several methodological considerations in examining this consent issue, specifically in measuring psychological outcomes within an expectancy and nocebo effect context. Moreover, our findings call into question how effective current informed consent risk-warnings are. Continuing to develop a strong empirical base regarding consent risk-warnings in psychological trauma-related research is important to IRBs, researchers, and participants.

Supplementary Files

Expecting Psychological Side-Effects: Risk-Management Protocol

The following list outlines measures we took to minimise the risk of harm to participants:

1. We included service referrals (e.g., hotline numbers) on the consent form and debriefing materials.
2. For this consent risk-warning investigation, we only had participants *believe* they would participate in the trauma-described study.
3. Participants were informed at the earliest time possible about our deception during consent. We provided a comprehensive debrief form that explained why the deception was necessary, given our aims. We also highlighted that our study was designed to be believable and so participants should not feel embarrassed if they believed the information they were originally given. Further, we made it clear that because of our deception, participants could opt to withdraw their data and that they would not be penalised in any way for doing so.
4. To ensure that participants understood the choice associated with data withdrawal, we administered two multiple choice questions. If participants got either of these questions wrong, we directed them to read the debriefing form again.
5. We presented participants with the true consent information associated with our research and offered them the choice to re-consent or not consent (i.e., withdraw data).
6. Because these data were collected online, we ensured that a researcher was online and regularly checking participant correspondence during data collection.
7. We used the “explicit content” tag on our online study.

Table S8

Descriptive Statistics for Warning Condition and Audio Type on Expected Distress

Warning Condition	Audio Type	
	Audio *M (SD)*	No Audio *M (SD)*
High risk-warning	42.33 (29.90)	52.70 (38.97)
Negligible risk-warning	21.92 (27.45)	33.70 (32.67)

Note. Expected distress is measured on a 0 to 100 scale (0 = not at all likely to experience distress and 100 = extremely likely to experience distress).

Chapter 9: Expecting the worst: Do informed consent risk-warnings cause negative outcomes for participants?

Author Contributions: I developed the study design with the guidance of MKTT and VMEB. I collected and cleaned the data, and performed the data analysis and interpretation. I drafted the manuscript and MKTT and VMEB provided critical revisions. All authors approved the final version of the manuscript for submission.

Abstract

Risk-warnings delivered as part of informed consent in psychological trauma-related research potentially cause negative outcomes for participants (e.g., Abu-Rus et al., 2019; Bridgland & Takarangi, 2021). For instance, risk-warnings might suggest psychological side-effects (e.g., distress) to participants, causing them to expect to experience, and subsequently manifest, these side-effects (*i.e., nocebo effects*; Benedetti et al., 2007). But, in a psychological trauma-related context, there is scant research addressing this possibility. Therefore, we randomly allocated participants (N = 200) to encounter a risk-warning (e.g., "you may experience distress") or no warning during informed consent procedures, prior to an online trauma analogue paradigm. Opposing expectations—and signalling good news for IRBs and researchers—we found no evidence to suggest participants experienced psychological nocebo effects (e.g., distress). Concerningly however, we found no difference between warning conditions for expected side-effects, suggesting that consent risk-warnings might not be working as intended. Overall, our findings have implications for how to warn participants in trauma-related research.

Introduction

Researchers use risk-warnings like "participating in this research may cause distress, including distressing memories for the week following" during the informed consent process to communicate potential risks—or side-effects—associated with participation. These well-

meaning risk-warnings feature in research areas that IRBs perceive as psychologically *sensitive* or risky (e.g., Yeater et al., 2012), including trauma-related research (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006). But risk-warnings may negatively affect participants via *nocebo-type responding* (e.g., Abu-Rus et al., 2019; Bridgland & Takarangi, 2021). That is, risk-warnings could *suggest* negative psychological side-effects (e.g., distress), causing people to expect those side-effects (e.g., expecting to feel distress; e.g., Michael et al., 2012; Webster et al., 2016; see also *response expectancy,* Kirsch, 1997). This expectation, in turn, may cause participants to manifest—or if pre-existing, worsen—the warned of negative side-effects (e.g., experiencing distress; Benedetti et al., 2007; Colloca, 2024). Therefore, we examined whether participants who encountered a consent risk-warning for a psychological trauma-related study were more likely to experience warned of side-effects than participants who did not receive a warning. This pattern would be evidence of a psychological nocebo effect.

IRBs must determine any risk of harm associated with trauma-related research and ensure these risks are communicated via informed consent (e.g., NHMRC, 2023). But this task is likely challenging. Trauma is a subjective experience (Jones & McNally, 2022; McNally, 2003). And, ethical guidelines can be vague, referring to harm, for example, as "an experience of re-traumatisation" without providing further clarification (NHMRC, 2023). Hence, IRB members may use subjective means to make decisions about risk, such as their "intuition" or own prior experiences (e.g., Haggerty, 2004; Smith & Anderson, 2022). Thus, risk-warnings in psychological trauma-related research may not reflect *objective risk* (Abu-Rus et al., 2019), meaning participants may encounter warnings for side-effects that are unlikely to occur (e.g., Jaffe et al., 2015).

Even when unlikely, side-effects may still occur *because* they have been suggested to participants via the informed consent process, as part of a risk-warning (e.g., Abu-Rus et al.,

2019; Becker-Blease & Freyd, 2006). Evidence from the medical-based nocebo literature supports this possibility (e.g., Benedetti et al., 2007; Colloca, 2024). For instance, in a systematic review of anti-migraine clinical trials, participants who received a placebo reported warned of side-effects (e.g., memory difficulties) that aligned with the true side-effects for anticonvulsant migraine medication (Amanzio et al., 2009). The authors proposed the side-effect information participants received during informed consent procedures caused participants to *expect* to experience such side-effects. In turn, these expectations led to participants experiencing the warned of side-effects. Other researchers have found that explicit suggestions about symptoms (e.g., TV reports showing first-person accounts of symptom reporting related to wind farms) are strong nocebo effect predictors (Crichton & Petrie, 2015; Webster et al., 2016), including for affective outcomes, like anxiety (Geers et al., 2021). Together, extant evidence from the medical literature suggests the risk-warnings used in trauma-related research could cause nocebo effects in participants.

One mechanism that explains how nocebo effects occur is *expectancy* (Rooney et al., 2023; Webster et al., 2016; though see Blasini et al., 2017 for other mechanisms). Expectancy is a type of *prospective* priming, whereby people encounter a prime stimulus *before* exposure to a related target (Minton et al., 2017). Here, for instance, risk-warnings about side-effects act as the prime, causing people to generate expectations about their reaction to participating in trauma-related research (i.e., the target). Consequently, participants might interpret their participation negatively, causing psychological side-effects, such as distress, to occur, in line with the prime (i.e., nocebo effect). One specific expectancy type, *response expectancies,* occurs when people anticipate their own behavioural reactions to external cues—like suggested side-effects—in an automatic way (Kirsch, 1985). Indeed, prior research shows suggestions can create response expectancies (Michael et al., 2012), and subsequent nocebo effects (e.g., Rooney et al., 2023). For example, participants who encounter negative pain

suggestions subsequently report expecting to experience pain, and in turn experience more pain (e.g., Elsenbruch et al., 2019; Lang et al., 2005). Moreover, in the related trigger warning literature (i.e., alerts that supposedly help people prepare and avoid upcoming material that may trigger memories/reactions connected to prior experiences), trigger warnings create a noxious anticipatory anxiety period—or negative expectancy—prior to encountering potentially negative content (Bridgland, Jones, et al., 2023).

Bayesian theory offers another way to conceptualise how risk-warnings cause nocebo effects. People have a base—or prior—world understanding, and when they encounter new evidence, they must balance such evidence against their previous understanding and update their prior accordingly (Ongaro & Kaptchuk, 2019). For instance, negative psychological side-effect information (i.e., new evidence) may cause someone to re-evaluate their existing prior (e.g., feeling calm) and heighten their sensitivity—or expectations—to negative feelings.

Prior empirical studies that manipulate informed consent information, including risk-warnings, provide mixed evidence for whether nocebo effects occur in the informed consent context (Stirling et al., 2023). Among evidence favouring nocebo effects (e.g., de Wied et al., 1997; Mao et al., 2021; Neukirch & Colagiuri, 2015; Senn & Desmarais, Study 1), Myers and colleagues' (1987) seminal study found participants who received medication and were warned of minor gastrointestinal (GI) side-effects—versus participants who were not—were more likely to report GI side-effects and cease participation. In a psychological outcome context, participants warned that an upcoming film contained violent material—relative to another group informed the violent material had been edited—reported more distress post-film (de Wied et al., 1997). Other evidence negates the idea that consent risk-warnings cause nocebo effects (e.g., Holzhüter & Hamann, 2020; Senn & Desmarais, 2006, Study 2; Wilhelm et al., 2018). For instance, side-effect reporting was similar amongst in-patients

provided with either consent side-effect *or* no side-effect information, alongside a known inactive pill (i.e., open-label procedure; Holzhüter & Hamann, 2020).

However, not only are findings mixed, but these studies have methodological limitations. Few use an appropriate control condition (i.e., no warning)—though understandably an ethically challenging design to pursue—and several studies measure indirect outcomes (i.e., side-effects that were *not* warned of), rather than direct outcomes (i.e., side-effects included in the warning; Stirling et al., 2023). It is therefore difficult to determine whether risk-warnings *cause* nocebo effects. Further, to the best of our knowledge, there exists no published research regarding consent risk-warnings and nocebo effects within a *psychological trauma-related research* context (though see Bussell, 2017 doctoral thesis).

Thus, we examined if consent risk-warnings cause psychological nocebo effects for participants in trauma related research via a chain reaction conceptualisation. That is, we tested whether participants exposed to warned of side-effects (i.e., suggestion) reported higher negative expectancies (i.e., response expectancy), and in turn, negative side-effects (i.e., nocebo effects). We randomly allocated online participants to view either a high risk-warning or no warning at consent, prior to completing an experimental psychological trauma study. We operationalised our no warning condition as: not warning participants about potential *psychological reactions* (e.g., distress), but still informing them they would view a trauma film, due to ethical requirements. We warned participants in our high risk-warning condition about potential side-effects, like feeling distressed and experiencing flashbacks.

We had three key hypotheses related to nocebo-type responding: first, we predicted that participants in the high-risk condition would have greater increases in anxiety and negative affect, and greater decreases in positive affect, than participants in the no warning condition; an interaction between warning condition and time, where time has a larger effect for the high-risk condition. Second, we expected participants in the high risk-warning

condition would report more intrusive memories for the analogue trauma film than participants in the no warning condition. Additionally, we thought participants in the high risk-warning condition would report their intrusions as being more negative (i.e., distressing, vivid, emotionally intense, unpleasant, unwanted, sense of nowness, negative emotions) and try to suppress them more, relative to participants in the no warning condition. Third, we predicted participants in the high-risk condition would report greater (i.e., higher mean agreement) perceived drawbacks and emotional reactions, and fewer (i.e., lower mean agreement) personal benefits, global evaluations and participation scores, relative to the no warning condition.

To assess the first outcome-related step in our nocebo effect-type chain, we also investigated participants' expectancies relating to warned of psychological side-effects. Thus, we expected: participants in the high-risk condition would report higher (i.e., more negative) post-participation expectations (i.e., our expectancy measure) regarding participation side-effects than participants in the no warning condition. Additionally, we predicted participants' pre-participation expectations would positively correlate with post-participation psychological reaction measures (i.e., our nocebo effect measure), where correlations for high risk-warning participants would be statistically larger than for no warning participants. Finally, we had a secondary interest in whether warning type affected nocebo effects via expectancy, and, because IRBs favour risk-warning use in psychological trauma-related research, we explored whether nocebo effect responses differed between warning conditions for people reporting and not reporting prior trauma exposure (in line with Criterion A for PTSD; APA, 2013).

Method

We pre-registered this experiment on the OSF (https://osf.io/y6kqb), where the data are publicly available (https://osf.io/9m76v/). We report all conditions, measures, and data

exclusions. The Flinders University Human Research Ethics Committee approved this study (6565).

Participants

We aimed to collect $N = 200$ usable participants for several reasons. First, for our primary analyses—mixed model ANOVAs and t-tests—G*Power recommends $N = 123$ (for repeated measures, within-between interaction ANOVA, with input: $\alpha = .05$, 80% power, $f = 0.20$) and $N = 200$ (for independent samples t-tests with input of $\alpha = .05$, 80% power, $d = 0.40$). For our correlational analyses, a sensitivity analysis (for correlation bivariate model, $\alpha = .05$, 80% power, and $N = 200$) showed we could reliably detect effects at $r = 0.17$ and above. We therefore were well-positioned to detect small-to-medium effects. Second, we reason detecting small-to-medium—and larger—effects is important because these effect sizes may indicate risk-warnings are having a detrimental impact on participants via nocebo effects. Finally, the proposed sample size fit within our resource capacity.

We collected 208 US-based participants using Connect, an online source of high-quality participants by Cloud Research (https://www.cloudresearch.com/products/connect-for-researchers/). We excluded five participants for responding to film-check questions incorrectly and three participants for responding to all article-related questions incorrectly. Our final sample comprised 200 participants, aged $M = 35.65$ years ($SD = 11.51$), who were mostly men (57%; women = 39.5%; non-binary = 2.5%; prefer not to say = 1%). Participants' self-reported ethnicity was mainly Caucasian/White (59.5%; African American/Black/Black American: 16%, Asian = 7.5%, Mixed/Biracial = 6%, Hispanic = 4%, Native American = 1.5%, Latino = 1.5% or Other [i.e., Afro Caribbean, Vietnamese, Chinese, Ashkenazi Jewish, Mexican, African, Scandinavian = 4%). Most participants had completed a bachelor's degree (38%), high school/equivalent (31.5%), associate

degree/diploma (16.5%), master's degree (10.5%), or doctoral studies (3%). Participants were compensated (US) $3.00 for participation.

Materials

Risk-Warning Manipulation

Participants encountered consent information containing a high risk-warning (i.e., "Because this study will involve graphic scenes involving a sexual assault, participants may experience feelings of distress [e.g., feeling upset, afraid, anxious]. Participants may also experience frequent sudden and intrusive memories about the film clip. These intrusive memories may feel distressing, unwanted, or vivid") or no risk-warning. Otherwise, the information sheet and consent forms were identical between conditions. To ensure participants processed the warning, they listened to a 1 minute AI audio clip that reiterated the study's purpose and risks. To divert attention from our true purpose, we told participants that our IRB required they listen to the clip because the study involved viewing a trauma film.

State Trait Anxiety Inventory Short Form (STAI-6; Marteau & Bekker, 1992)

We examined participants' anxiety by asking them to rate how they felt in the present moment across six stress-related items (e.g., "I am worried", "I feel calm"; *1 = Not at all, 4 = Very much*). Anxiety-absent items were reverse-scored, and scores were summed (range: 6-24), with higher scores reflecting greater anxiety. The STAI-6 has good internal consistency $\alpha = .82$ (current study: $\alpha = 0.88$), produces similar mean scores to the full-form STAI (Marteau & Bekker, 1992), and has been previously used in warning studies (e.g., Bridgland et al., 2019). We conceptualised the STAI-6 as a direct measure of nocebo effects because participants were warned about feeling anxious due to participation.

Positive and Negative Affect Scale (PANAS; Watson et al., 1988)

To measure participants' affect, they rated 10 positive affect (e.g., "Interested") and 10 negative affect (e.g., "Distressed") items on a 5-point scale (where *1 = Very slightly or not at all and 5 = Extremely*) based on how they presently felt. Scores were summed (range: 10 – 50), with higher scores reflecting greater negative or positive affect. The PANAS has good internal consistency (positive scale: $\alpha = .86$ to $\alpha = .90$, current study: $\alpha = 0.92$; negative scale: $\alpha = .84$ to $\alpha = .87$, current study: $\alpha = 0.91$; Watson et al., 1988). We considered the PANAS as an indirect measure of nocebo effects because participants were not warned about feeling more positive/negative.

Participation Expectations Questionnaire

We adapted Faasse, Huynh et al.'s (2019) Treatment Expectations Questionnaire and asked participants to rate five statements regarding their expectations for the study (e.g., "How likely are you to experience psychological side-effects [e.g., distress] because of participation in this study?") on an 11-point scale (where *0 = Not at all and 10 = Extremely*). Three of the five statements were filler items to disguise the two statements we were interested in (i.e., items relating to psychological side-effects and experience of intrusive memories).

Trauma Film Paradigm (James et al., 2016)

Participants viewed a 6-minute scene from *The Accused* (1988), depicting a gang rape (e.g., Lepore et al., 2004; Takarangi et al., 2017).

Reading and Monitoring Task (Appendix I)

Participants spent 5-minutes reading two science-related articles (i.e., about stars and time) and were asked to press X each time they experienced a film-related intrusive thought. Prior research uses this task to measure participant's intrusive memories (e.g., Green et al., 2016).

Phenomenological Experience of Intrusions (Appendix J)

Participants who reported experiencing intrusion(s) rated how distressing, vivid, intense, intrusive, unpleasant, and unwanted those intrusions were; the here and now quality of the intrusions; and their suppression effort (Hackmann et al., 2004). All items were rated on an 8-point scale (where *0 = Not at all and 7 = Extremely*; except for type of emotion where *0 = Extremely negative and 7 = Extremely positive*).

Trauma-Related Questions

To examine participants' prior trauma exposure—according to Criterion A for PTSD diagnosis (APA, 2013), we asked them to remember their most traumatic or stressful event and whether if, during this event, they were exposed to death, actual or threatened injury, or actual or threatened sexual violence, in any of the following way(s): a) direct exposure, b) witnessing the trauma, c) learning that a relative or close friend was exposed to a trauma, d) indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g., first responders). Participants responded Yes, No, or Prefer Not to Say.

To assess whether the content depicted in the trauma film aligned with participants' prior traumatic experiences, we asked participants whether they had personal experience with the topic of the film they viewed (Y/N/Prefer Not to Say).

Reactions To Research Participation Questionnaire (RRPQ; Newman et al., 2001; Appendix K)

We measured participants' research participation experience by asking them to rate 23 statements across five domains: participation (e.g., "I like the idea that I contributed to science"; current study: $\alpha = 0.65$), personal benefits (e.g., "I gained something positive from participating"; current study: $\alpha = 0.86$), emotional reactions (e.g., "This research raised emotional issues for me that I had not expected"; current study: $\alpha = 0.85$), perceived drawbacks (e.g., "I found the questions too personal"; current study: $\alpha = 0.76$), and global

evaluations (e.g., "I believed the study's results will be useful to others"; current study: α = 0.73), using a 5-point scale (where *1 = Strongly disagree and 5 = Strongly agree*). Per Newman et al., we reverse-scored two perceived drawbacks items, with higher scores indicating greater agreement with the statement/participation experience domain. We additionally conceptualised the RRPQ as an indirect measure of nocebo effects.

Suspicion Questionnaire

We asked participants several open text questions to examine what they believed our study's purpose was and whether they believed we expected them to react/respond in a particular way.

Procedure[37]

Because we conducted data collection online, participants had to complete a captcha screen, cultural-check question, and score 80% or above on an English proficiency test (see Moeck et al., 2022 and https://www.cloudresearch.com/products/connect-for-researchers/ for participant quality information). As part of our cover story, we told participants we were interested in their personality traits and how they interacted with their response to emotional material. We randomly allocated participants to view the high-risk or no warning information and consent forms; high-risk participants also listened to the audio clip as part of this consent process. Participants who consented responded to the STAI-6, PANAS, Ten Item Personality Inventory (Ehrhart et al., 2003),[38] Participation Expectations Questionnaire, and demographics (e.g., age, education, self-reported ethnicity, gender).

Next participants viewed the trauma film and answered film-related attention check questions. Participants completed the reading and monitoring task and responded to article attention check questions. Participants who reported experiencing intrusions reported the

[37] We used several strategies to ensure participants were aware of the study's nature and that they had appropriate supports available while completing the study. Please see Supplementary Files at the end of this Chapter or https://osf.io/9m76v/ for these protocols in full.

[38] To increase our cover story's believability, we administered the TIPI. We do not examine these data.

phenomenological characteristics of these intrusions. Next, all participants responded to the STAI-6, PANAS, single-item trauma-related questions, and RRPQ. We debriefed participants, and to help repair their mood, asked them to recall a past experience that made them feel proud (e.g., Seebauer et al., 2016).

Statistical Overview

We ran frequentist statistical analyses using SPSS 29. Per pre-registration, we calculated Bayes Factors (BF) using JASP (Version 0.15), using Cauchy default priors (0.707). We followed Wetzels et al.'s (2011) guidelines for interpretation.

Arguably, some of our dependent variables may form a statistical family (e.g., intrusion characteristics). However, we did not apply corrections below because they would not have changed our overall interpretation of results.

Results

Do High-Risk Consent Warnings Cause Psychological Nocebo Effects?

We first conducted two independent t-tests on participants' baseline PANAS (i.e., negative and positive affect) and anxiety scores to check whether warning conditions differed. They did not (*t*s: 0.40 – 1.16, *p*s: .218 - .689).

We then considered participants' reported anxiety and affect after viewing the warning (i.e., post-warning) and post-participation (i.e., after completing the *trauma* participation section of our experiment). Overall, irrespective of warning type, participants' reported anxiety and negative affect significantly increased, and positive affect significantly decreased, from post-warning to post-participation; significant main effects for time, *ps* < .001 (see Table 9.1 for relevant descriptive and inferential statistics). However, opposing our predictions, we did not find that participants who encountered the high risk-warning reported more negative outcomes (e.g., greater anxiety) than participants who encountered no warning at any time point; a nonsignificant condition by time interaction for anxiety, $F(1, 198) = 0.81$,

$p = .370$, $\eta_p^2 = 0.004$, negative affect scores, $F(1, 198) = 0.68$, $p = .410$, $\eta_p^2 = 0.003$, or positive affect scores, $F(1, 197)$[39] $= 0.41$, $p = .521$, $\eta_p^2 = 0.002$ (see Table 9.1 for results in full, including main effects). Likewise, our BF analyses revealed substantial evidence in favour of the null—over the alternative hypothesis (i.e., that there was a difference over time between warning conditions)—for anxiety, and negative and positive affect.

Turning to our direct—and somewhat more objective—intrusion frequency measure, overall, 135 participants reported experiencing intrusions during the reading task (high risk-warning: 66, no warning: 69). Because the number of participants reporting intrusions fell below our target sample size, we ran a sensitivity analysis using G*Power to determine at what effect size we could reliability detect effects for intrusions ($\alpha = .05$, 80% power, respective group sizes). Our analysis showed we could detect small-to-medium effects ($d = 0.49$) and above. We also detected one extreme univariate outlier (intrusion frequency = 142) at the high end of potential intrusions within our 5-minute monitoring period. We adjusted this score so that it fell one point away from the next lowest score before running analyses (Tabachnick & Fidell, 2007).

We ran several independent samples t-tests to determine whether our warning conditions differed on reported intrusions and associated intrusion characteristics. Against predictions, participants who viewed the high risk-warning—versus no warning—did not report greater intrusion frequency[40] or more negative (i.e., higher) intrusion-associated characteristics, like vividness (see Table 9.2 for descriptive and inferential statistics). But we note that for some analyses, *d*s fell below the threshold of effect sizes we could reliably

[39] One participant did not respond to the positive affect items in the no warning condition, hence there are 99 participants in this condition for analyses.

[40] Because it may be more appropriate to analyse count data, such as intrusion frequency, using negative binomial regression (e.g., Green, 2021), we ran this analysis (deviance > 1) with warning condition as the predictor and intrusion frequency the dependent variable. Our analysis confirmed that warning condition did not significantly predict intrusion frequency ($p = .194$). We report *t*-tests in the main text because they were our pre-registered analyses.

detect, and thus, we interpret with caution. Our BF analyses showed anecdotal to substantial evidence in favour of the null hypothesis, over the alternative.

Contrary to predictions, we found no evidence of nocebo effects across research experience domains: perceived drawbacks, emotional reactions, personal benefits, global evaluations, and participation (i.e., nonsignificant difference between warning conditions; see Table 9.2 for results in full). Our BF analyses revealed anecdotal to very strong evidence in favour of the null hypothesis, over the alternative.

Table 9.1

Descriptive, Inferential, and Bayes Factor Statistics for Mixed-Model ANOVA Results

	High Risk-Warning		No Warning						
	Time 1 *M (SD)*	Time 2 *M (SD)*	Time 1 *M (SD)*	Time 2 *M (SD)*	*(df) = F, p*	η_p^2	BF_{10}	Condition Main Effect *(df) = F, p,* η_p^2	Time Main Effect *(df) = F, p,* η_p^2
Anxiety	10.14 (4.07)	14.42 (5.42)	9.92 (3.68)	14.82 (5.01)	(1, 198) = 0.81, .370	0.004	0.23	(1, 198) = 0.03, .870, 0.00	(1, 198) = 176.64, .001, 0.47
Negative Affect	13.33 (4.98)	18.44 (8.82)	13.99 (6.83)	19.99 (9.01)	(1, 198) = 0.68, 410	0.003	0.22	(1, 198) = 1.42, .235, 0.007	(1, 198) = 106.08, .001, 0.35
Positive Affect	28.69 (9.26)	22.64 (8.74)	30.25 (9.84)	24.86 (9.95)	(1, 197) = 0.41, .521	0.002	0.18	(1, 197) = 2.33, .129, 0.01	(1, 197) = 125.56, .001, 0.39

Table 9.2

Descriptive and Inferential Statistics, including Bayes Factors, for Between Group Comparisons on Expectancy Measures and Nocebo Effect Outcomes

Nocebo Measure	High Risk-Warning	No Warning				
	M (SD)	*M (SD)*	*p*	*Cohen's d*	BF_{10}	BF_{10} *Interpretation (for null)*
Intrusion Frequency	10.20 (13.83)	8.00 (9.59)	.288	0.19	0.41	Anecdotal evidence
Intrusion: Distressing	4.08 (2.09)	4.39 (2.16)	.391	0.15	0.12	Substantial evidence
Intrusion: Spontaneous	4.97 (1.70)	5.17 (1.65)	.481	0.12	0.12	Substantial evidence
Intrusion: Effortful	5.12 (1.76)	5.28 (1.64)	.599	0.09	0.13	Substantial evidence
Intrusion: Vivid	4.91 (1.98)	4.93 (1.61)	.953	0.10	0.18	Substantial evidence
Intrusion: Emotionally Intense	4.32 (2.07)	4.17 (2.08)	.687	0.07	0.26	Substantial evidence
Intrusion: Unpleasant	5.18 (1.90)	5.17 (1.89)	.981	0.004	0.19	Substantial evidence
Intrusion: Unwanted	5.67 (1.66)	5.75 (1.61)	.758	0.05	0.15	Substantial evidence
Intrusion: Nowness	3.76 (2.18)	3.30 (2.09)	.220	0.21	0.65	Anecdotal evidence
Intrusion: Type of Emotion	0.79 (1.10)	0.90 (1.13)	.565	0.10	0.13	Substantial evidence
Intrusion: Suppression	5.15 (1.77)	4.87 (2.06)	.396	0.15	0.41	Anecdotal evidence
Perceived Drawbacks	12.44 (4.00)	12.36 (4.21)	.891	0.02	0.17	Substantial evidence
Emotional reactions	13.17 (3.97)	14.01 (3.93)	.134	0.21	0.07	Very strong evidence
Personal Benefits	11.97 (3.51)	11.40 (4.04)	.288	0.15	0.44	Anecdotal evidence
Global Evaluations	20.99 (2.83)	21.26 (2.78)	.497	0.10	0.10	Strong evidence
Participation	16.77 (2.30)	16.76 (2.40)	.976	0.004	0.16	Substantial evidence
Neg. Side-Effect Expectancy	3.15 (2.91)	2.49 (2.63)	.094	0.24	1.09	No evidence
Increased Intrusion Expectancy	3.13 (3.03)	2.64 (2.63)	.224	0.17	0.54	Anecdotal evidence

In summary, our findings do not indicate that informed consent risk-warnings used in psychological trauma-related research cause nocebo effects for participants. In fact, the warning had minimal effect on psychological "side-effects" (e.g., anxiety, intrusion frequency), whether these outcomes were direct (i.e., warned of) or indirect (not warned of). One potential reason we did not observe nocebo effects is because participants' expectancies did not first change; that is, the first step in our nocebo effect-type chain was not realised. To test this possibility, we next examined whether the risk-warnings altered participants' expectancies.

Do Participant Expectancies Predict Nocebo Effects?

Here, we predicted that participants in the high risk-warning condition would report higher (i.e., more negative) expectations about psychological side-effects than participants in the no warning condition. Against predictions, and consistent with our previous work (Stirling et al., 2024), we found no significant differences between warning conditions on any expectancy item (i.e., more negative side-effects or increased intrusions), *ps*: .094 - .224 (see Table 9.2 for results in full). Our results therefore suggest that we did not observe nocebo effects because participant expectancies did not differ; that is, the first step in our nocebo effect chain was not realised.

However, to exclude the possibility that consent risk-warnings affect participants, we examined the relationship between expectancies and nocebo effects, and subsequently whether this relationship differed between warning conditions. First, we predicted that participants' expectations would correlate with their post-participation psychological reactions (i.e., our nocebo effect measures). Overall, our prediction was partially supported: participants' expectations correlated with some psychological outcomes, such as negative affect, positive affect, and intrusion frequency, together with some intrusion characteristics (e.g., intrusion was distressing, intrusion was emotionally intense; refer to Tables 9.3 and

9.4). However, we also predicted that these correlations would be statistically larger among our high risk-warning participants compared to no warning participants. We found some evidence to support our predictions. For expected negative psychological side-effects, the correlation with post-warning anxiety scores was larger for warning than no warning participants, $Z = 2.20$, $p = .028$. For expected intrusion frequency, the correlations with post-warning anxiety ($Z = 2.69$, $p = .007$), post-warning positive affect ($Z = -2.27$, $p = .023$), intrusion frequency ($Z = 2.14$, $p = .032$), intrusion effort ($Z = 2.01$, $p = .044$), and intrusion spontaneity ($Z = 2.07$, $p = .039$), were larger for warning than no warning participants. All other comparisons were nonsignificant, *p*s: .066 - .803. Therefore, these findings suggest that the risk-warning is having a small effect on participants.

Table 9.3

Correlation Matrix Examining Participant Expectancies with Nocebo Outcome Measures (Overall Sample)

Variable	1	2	3	4	5	6	7	8	9	10	11
1. Neg. Side-Effect Expectancy	—										
2. Increased Intrusions Expectancy	.83*** [.79, .88]	—									
3. Participation	-.26*** [-.39, -.13]	-.27*** [-.40, -.14]	—								
4. Perceived Benefits	-.09 [-.22, .05]	.02 [-.12, .16]	-.42*** [.30, .53]	—							
5. Emotional Reactions	.37*** [.24, .48]	.29*** [.16, .41]	.-.11 [-.24, .03]	-.01 [-.15, .13]	—						
6. Perceived Drawbacks	.34*** [.22, .46]	.34*** [.22, .46]	-.69* [-.76, -.61]	-.42*** [-.53, -.30]	.16* [.03, .30]	—					
7. Global Evaluations	-.10 [-.23, .04]	-.12 [-.25, .02]	.69*** [.61, .76]	.35*** [.22, .47]	.14 [-.001, .27]	-.61*** [-.69, -.52]	—				
8. Post-Participation STAI	.37*** [.25, .49]	.30*** [.17, .42]	-.28*** [-.40, -.14]	-.32*** [-.44, -.19]	.57*** [.47, .66]	.34*** [.22, .46]	-.04 [-.18, .10]	—			
9. Post-Participation Neg. PANAS	.42*** [.30, .53]	.37*** [.25, .49]	-.26*** [-.39, -.13]	-.12 [-.26, .02]	.55*** [.45, .64]	.40*** [.28, .51]	-.09 [-.22, .05]	.78*** [.72, .83]	—		
10. Post-Participation Pos. PANAS	-.21** [-.34, -.07]	-.10 [-.24, .49]	.25*** [.11, .38]	.52*** [.41, .61]	-.11 [-.25, .03]	-.27*** [-.40, -.14]	.21*** [.07, .36]	-.55** [-.64, -.45]	-.24*** [-.37, -.10]	—	
11. Intrusion Frequency	.22*** [.09, .35]	.16* [.03, 30]	-.19** [-.32, -.06]	-.14* [-.28, -.004]	.22** [.08, .35]	.17* [.03, .30]	-.12 [-.24, .03]	.32*** [.19, .44]	.34*** [.22, .46]	-.25*** [-.37, -.11]	—

Note: (***) indicates correlation is significant at the $p < .001$ level, (**) indicates correlation is significant at the .01 level, (*) indicates correlation is significant at the .05 level.

Table 9.4

Correlation Matrix Examining Participant Expectancies with Intrusion-Specific Nocebo Outcome Measures (Only Participants Reporting Intrusions)

Variable	1	2	3	4	5	6	7	8	9	10	11	12
1. Neg. Side-Effect Expectancy	—											
2. Increased Intrusions Expectancy	.83*** [.79, .88]	—										
3. Intrusion: Spontaneous	.10 [-.08, .26]	.04 [-.13, .21]	—									
4. Intrusion: Effortful	.09 [-.08, .26]	.05 [-.13, .21]	.75*** [.66, .81]	—								
5. Intrusion: Distressing	.30*** [.14, .45]	.27** [.10, .42]	.46*** [.31, .58]	.43*** [.28, .56]	—							
6. Intrusion: Vivid	.22** [.06, .38]	.18* [.01, .34]	.58*** [.46, .68]	.54*** [.41, .65]	.70*** [.61, 78]	—						
7. Intrusion: Emotionally Intense	.36*** [.20, .50]	.31*** [.15, .46]	.47*** [.33, .60]	.41*** [.26, .54]	.87*** [.82, .91]	.74*** [.65, .81]	—					
8. Intrusion: Nowness	.30*** [.14, .45]	.31*** [.15, .45]	.36*** [.20, .50]	.27** [.11, 42]	.63*** [.51, .72]	.59*** [.47, .69]	.71*** [.62, .79]	—				
9. Intrusion: Unpleasant	.32*** [.16, .46]	.24** [.08, .40]	.36*** [.20, .50]	.31*** [.15, .46]	.79*** [.72, .85]	.63*** [.51, .72]	.78*** [.71, .84]	.62*** [.50, .71]	—			
10. Intrusion: Unwanted	.22** [.05, .37]	.16 [-.01, .32]	.40*** [.25, .53]	.42*** [.28, .55]	.61*** [.49, .71]	.52*** [.38, .63]	.58*** [.46, .69]	.38*** [.22, .51]	.71*** [.62, .79]	—		

11. Intrusion: Type of Emotion	-.15 [-.31, .02]	-.10 [-.27, .07]	-.29*** [-.44, -.13]	-.25** [-.40, -.08]	-.53*** [-.64, -.40]	-.46*** [.-.59, -.31]	-.57*** [-.68, -.45]	-.51*** [-.62, -.37]	-.55*** [-.66, -.42]	-.45*** [-.58, -.31]	—	
12. Intrusion: Suppression	.15 [-.20, .31]	.17* [.004, .33]	.31*** [.15, .46]	.32*** [.16, .46]	.57*** [.45, .68]	.53*** [.40, .64]	.53*** [.40, .64]	.40*** [.25, .53]	.55*** [.42, .66]	.49*** [.36, .61]	-.52*** [-.64, -.39]	—

Note: (***) indicates correlation is significant at the $p < .001$ level, (**) indicates correlation is significant at the .01 level, (*) indicates correlation is significant at the .05 level.

Finally, we pre-registered that we would run exploratory mediated regression analyses to determine whether risk-warning type affected nocebo effects via participant expectancies. We found no evidence to suggest that warning type mediated nocebo effect occurrence via expectancies across any of our variables. Thus, for the interested reader, see https://osf.io/9m76v/. We suspect that we found a different pattern of results between our mediation and size of correlation comparison analyses because the mediation combined the warning conditions (i.e., predictor). As such, these data were likely noisier, meaning small effects were harder to detect.

Does Prior Trauma Exposure or Exposure Type Matter?

Of our sample, 134 participants reported experiencing and 48 not experiencing a Criterion A traumatic event; eight participants preferred not to say. Additionally, 35 participants said that their reported traumatic event matched the traumatic event depicted in the film (155 responded no to this question and 10 participants preferred not to say). We proceeded with exploratory between-subjects ANOVAs, though we note our analyses were not adequately powered to detect small-to-medium effects and thus should be interpreted with caution. Overall, we found no significant interaction between warning condition and Criterion A exposure status across any psychological outcome (i.e., nocebo effect) measure, except for intrusion effort. Numerically, non-trauma-exposed participants who did not encounter the warning reported that intrusions came to mind with effort, more so than the other condition. Pairwise comparisons were however nonsignificant. Moreover, warning condition and trauma match status did not interact for any psychological outcome measure. See https://osf.io/9m76v/ for results reported in full. Thus, our results indicate that informed consent risk-warnings similarly affect participants, regardless of prior trauma-exposure or whether their traumatic event matched the film.

Discussion

Recall, we had two primary aims. First, to examine whether participants who received a high-risk consent warning for an online trauma-related study reported more adverse outcomes (i.e., nocebo effects)—comprising direct (i.e., warned of outcome) and indirect (i.e., not warned of outcome) outcome measures—than participants who received no such warning. Our findings did not support this possibility. Second, to investigate whether risk-warnings provided during consent altered participants' negative expectancies for warned of psychological side-effects. Again, our findings did not support this idea; in fact, overall expectancies were low (i.e., participants did not expect to experience warned of side-effects). Hence, our proposed nocebo effect-type chain for informed consent risk-warnings was not realised. Together, these findings indicate that informed consent risk-warnings in psychological trauma-related research neither cause nocebo effects (i.e., adverse outcomes) nor increase peoples' negative expectancies for warned of psychological side-effects.

However, the relationship between participants' expectancies and psychological outcomes (e.g., anxiety) was larger for participants who encountered a high risk-warning (versus no warning). While our correlational comparisons may not have been adequately powered (e.g., $N = 260$ is suggested by Schönbrodt and Perugini, 2018 for correlations)—and so we interpret with caution—our findings suggest that high-risk consent warnings have *some* effect on participants. There are at least two interpretations of these data. First, perhaps participants who encountered the high risk-warning experienced heightened sensitivity to negative feelings—in line with Bayesian theory (Ongaro & Kaptchuk, 2019)—relative to no warning participants. For instance, side-effects suggested via the risk-warning may have caused participants to re-evaluate their emotional responses—in line with the suggested side-effects— and update their prior (e.g., "participation is making me anxious"), making participants more likely to experience negative feelings. Potentially this heightening was a

small effect and only detectable within-subjects (e.g., when participants' own expectancy responses were considered with their psychological outcome responses), hence why we did not detect between-group differences. Second, if our expectancy measures are conceptualised as predictions and our nocebo effect measures as emotional outcomes (Coteţ & David, 2016), then we would expect some association between the two, irrespective of warning encountered. Perhaps then, the risk-warning—containing specific information about emotional predictions—improved participant's prediction accuracy, as reflected through the stronger relationship between expectancy and nocebo effect outcome (Coteţ & David, 2016).

Our overall findings, for both negative expectancies and nocebo effects, run counter to evidence from the medical literature that the informed consent process contributes to nocebo effects (e.g., Colloca, 2024). Possibly, the side-effect types and/or suggestions made during the informed consent process for psychological outcomes are less potent than for medical outcomes. Or, perhaps the outcomes themselves are important (e.g., trauma is more subjective than a potential physical symptom, like nausea). Of course, some other key differences between the medical literature and our study include having no discrete nocebo vehicle (e.g., inactive pill, sham electrode treatment) that participants could attribute our side-effect suggestions to, exclusively measuring psychological outcomes (versus reported pain, for example), and conducting our study online (versus in-person). But our findings are also inconsistent with the few published informed consent studies examining psychological outcomes (de Wied et al., 1997; Senn & Desmarais, 2006). Again, we note methodological differences with this previous work that was not *trauma-related,* and where participants generally responded about their reaction to *content* rather than their own psychological reactions (i.e., as a warned of side-effect). Hence, these methodological and contextual differences may account for our alternative findings.

There are at least two other possibilities for why our findings ran counter to predictions. First, we placed our expectancy measure *prior* to our psychological outcome measures. By first measuring participant expectancies, we may have primed *all* participants to the possibility of experiencing psychological side-effects. Consequently, participant reports on psychological outcome measures were similar between warning conditions. Future research could retrospectively measure participant expectancies post-nocebo measurement; though this method also has limitations (see Barnes et al., 2023).

Another possibility for why our predictions were unsubstantiated relates to individual difference factors. Perhaps an individual difference factor—aside from the exploratory trauma-related factors we assessed (i.e., prior trauma exposure and trauma experience match to the film)—was at play. For instance, there is some evidence trigger warnings affect participants' anticipatory negative affect more depending on whether participants feel trigger warnings protect or coddle them (Gainsburg & Earl, 2018).

Despite our findings—or lack thereof—our work adds to the similar growing field of trigger warning research (e.g., Bridgland et al., 2019). We extend understanding that warnings delivered during the informed consent process do not cause negative outcomes for participants and additionally show—counter to trigger warning anticipatory anxiety findings—that risk-warnings do not meaningfully increase people's negative expectancies (Bridgland et al., 2023). Further, our findings add to an increasing body of evidence that warnings do not help mitigate—or emotionally prepare people—to encounter potentially negative content or experiences (Bridgland et al., 2023).

To some IRBs' and researchers' relief then, the informed consent risk-warnings used in psychological trauma-related research do not appear to cause adverse outcomes for participants. While we encourage caution given our sample sizes for these data subsets, our analyses suggest risk-warnings do not differentially affect trauma-exposed people, including

people who report their prior trauma matches the film content. Hence, IRBs and researchers are likely not violating the ethical *beneficence* principle because participants are not experiencing harm. But our findings hint that informed consent risk-warnings are not achieving their intended purpose either.

Our findings call into question how effective informed consent risk-warnings are. If risk-warnings were working as intended, we would expect to see some difference in expectancy—even if statistically small—between people who encountered a risk-warning and people who did not. Like in our prior work, consent risk-warnings did not increase participants' expectancies for psychological side-effects (Stirling et al., 2024). This pattern is concerning, because some IRBs and researchers rely on risk-warnings as a harm mitigation strategy (e.g., Becker-Blease & Freyd, 2006), and participants typically report deciding to participate *prior* to encountering informed consent processes (Cook & Hoas, 2011). Thus, it is unlikely participants change their mind about participation at the point of viewing the risk-warning. Even if participants actively used the risk-warning to guide their decision-making—though this is unlikely given our prior finding that all participants chose to participate after viewing the warning (Stirling et al., 2024)—we know that people are not generally good at predicting their future emotions (e.g., Wilson & Gilbert, 2005). Anecdotally, this prediction error aligns with what we sometimes—albeit rarely—observe during data collection, where participants refer to being surprised by their reaction to viewing a trauma film. Certainly, current informed consent processes—for psychological research—may set people up to experience *unexpected emotion,* which could itself contribute to negative outcomes for participants. For instance, there is some evidence that a small subset of people who report feeling *distressed* do so because their reaction was unexpected (e.g., Newman et al., 2006). To prevent unexpected distress, as a first step, it is therefore important to ensure that participants in psychological trauma-related research understand and take potential risks on

board. Future research should continue to investigate the best way to achieve this goal (e.g., by making consent more interactive, considering how to update people's expectations of participation in trauma-related research).

Limitations

Our study has limitations. First, for experimental control purposes, we used an audio clip to ensure participants were exposed to the risk-warning. Not only did we deviate from traditional online informed consent processes (i.e., ecological validity), but listening to the risk-warning potentially had an unintended effect on people (e.g., feeling more supported by researchers/institution because we highlighted risk information). Future research could use alternative approaches (e.g., getting participants to initial next to each warned of side-effect; see Barnes et al., 2023). Second, due to our study design, we did not obtain pre-warning—or true baseline—psychological measures (e.g., anxiety) for participants. Thus, we could not assess the possibility that participants who encountered the risk-warning (versus those who did not) report a great *change* in psychological measures, such as anxiety or negative affect. However, given we investigated this possibility in prior work (Stirling et al., 2024), we doubt that incorporating baseline measures would change the interpretation of our findings. Third, because of ethical constraints, we informed all participants about the film's *nature* (i.e., gang rape/sexual assault). Thus, perhaps people had pre-existing expectations about how they would respond to viewing a potentially traumatic film, meaning that warning people of specific potential side-effects had minimal effect. Fourth, our study's findings are limited to an online setting, and a short period (i.e., nocebo effects manifesting during participation). Perhaps nocebo effects emerge over time (e.g., 2 weeks later), as some prior trigger warning research has found for the emotional impact (e.g., having trouble staying asleep) associated with negative memories (Bridgland & Takarangi, 2021). This possibility also fits with retrospective priming theories suggesting people must first be exposed to the prime *and* target

(e.g., participation) before priming occurs (e.g., Minton et al., 2017). Finally, although our study was available to all US residents on Connect, just over two-thirds of our sample self-reported their ethnicity as White and most of our sample was well-educated. Thus, the generalisability of our findings is limited to this sample type and future research should aim to replicate our findings in a more representative sample.

Constraints on Generality

Aside from limitations outlined above, we have no reason to believe our results depend on certain participant characteristics, materials, or procedures. Therefore, we believe our results would replicate with similar participants (i.e., crowdsourced online participants who elect to complete trauma-related research participation), similar consent and risk-warning stimuli, and on similar psychological outcome measures (e.g., affect, anxiety). We believe our results are likely confined to warnings delivered *as part of* the informed consent process, given our diverging results to prior trigger warning literature (i.e., where warnings are delivered *within* the study procedure).

Conclusion

Overall, consent risk-warnings used in a trauma-related research study did not change participant expectancies or cause psychological nocebo effects. Additionally, risk-warnings did not differentially affect participants reporting prior trauma exposure, including when this exposure matched the trauma film. Our findings however raise concerns over how effective risk-warnings in trauma-related research are in guiding participant decision-making during the informed consent process. Given some IRBs and researchers rely on risk-warnings as a harm mitigation strategy, future research should continue to investigate how effective informed consent risk-warnings are, in psychologically sensitive research areas.

Supplementary Files

Expecting the Worst: Risk-Management Protocol

The following list outlines measures we took to minimise the risk of harm to participants:

1. We used the 'contains sensitive content' tag on Cloud Research's Connect platform to signal to participants the nature of the study.
2. Because these data were collected online, we ensured that a researcher was online and regularly checking participant correspondence during data collection.
3. We included service referrals (e.g., hotline numbers) on the consent form and debriefing materials.
4. As a participation requirement, we directed participants to download our lab's mental health support form prior to participating. This form contained information regarding immediate support (e.g., 911), other forms of support (e.g., talking to a friend, talking to a helpline volunteer), and ideas for seeking professional help (e.g., psychologist, general practitioner).
5. On every page of our survey, we had a link to mental health support services if participants felt they needed to access support.
6. Prior to participants viewing the trauma film, we informed them that they could exit the film at any stage. We also included this reminder on the survey page that showed the trauma film.
7. We reinforced to participants that they could withdraw at any point without penalty by exiting the survey window.
8. To help mitigate potential negative effects of encountering the trauma film paradigm, at the end of participation, we provided participants with a mood repair activity (i.e., by asking them to recall a prior event that made them feel proud).

Chapter 10: General Discussion

The overarching aim of my thesis was to extend understanding of ethical issues that arise through the conduct of psychological trauma-related research. To achieve this aim, I addressed three specific concerns, which I framed as research questions. This concluding chapter summarises my findings—in relation to each research question—and discusses these findings in the context of prior research. Finally, I discuss overarching methodological, theoretical, practical, and clinical implications of my findings, together with limitations of my research.

Research Question One: How risky is participation in experimental—or analogue—trauma research?

Previous research has examined—across various populations (i.e., clinical, community, undergraduate)—how participants react to participating in trauma-related research; predominantly, this research asks participants to recall their prior traumatic experience(s) (e.g., Carter-Visscher et al., 2007; Edwards et al., 2009; Edwards et al., 2013; Jaffe et al., 2015; Yeater et al., 2012). However, this prior work has not considered other trauma-related research participation, such as analogue or experimental trauma-related research. Therefore, we do not know how risky analogue trauma-related research is. Below, I discuss how my work indicates that participating in analogue trauma-related research fits with minimal-risk of harm definitions—or is not as risky as some people might think.

Recall I focused on this research in Chapter 3, but Chapter 9 also provides evidence about the risk associated with analogue trauma-related research. Indeed, across these chapters, there are at least four ways my work suggests that analogue trauma-related research conducted with undergraduate students and crowdsourced participants does not exceed *minimal-risk* or *discomfort* harm definitions (Study 1; Chapter 3). First, extending on previous trauma-related questionnaire research (Yeater et al., 2012), I found that participants

do not consider analogue trauma participation as being worse than everyday stressors (e.g., having a cavity filled by a dentist). Moreover, in some instances (i.e., negative affect, mental costs), I found that participants who completed cognitive tasks and participants who viewed the analogue trauma film had comparable reactions to participation. Interestingly, IRBs may consider cognitive tasks as being less risky than trauma-related research (Yeater et al., 2012). Nevertheless, my data show that analogue trauma research fits with the minimal-risk harm standard. Second, my findings fit with previous research finding participants generally report low-to-moderate distress, as well as benefits, to participating in trauma-related research (Study 1; e.g., answering trauma-related questionnaires; Jaffe et al., 2015), and extend these findings to an analogue trauma context. Third, my work builds on prior research that also finds—contrary to IRB concern—that undergraduates generally tolerate trauma-related research participation well—for example, by reporting low negative emotion or that benefits outweighed participation costs (e.g., DePrince & Chu, 2008; DePrince & Freyd, 2006; Yeater et al., 2012). Finally, like previous trauma questionnaire research (Cromer et al., 2006; Yeater et al., 2012), my work (Study 1) suggests that analogue trauma research is not inherently riskier—or more distressing—than other psychological research areas or topics (e.g., cognitive tasks, SAT/GPA).

Exploratory data from Study 4 (Chapter 9)—that was not part of my original aims and analysis in this chapter—further highlights that analogue trauma-related research meets *discomfort* harm definitions, here for *crowdsourced* participants.[41] There are at least three key findings from these exploratory data (Study 4, Chapter 9).

First, participants—on average—indicated disagreement or neutrality—based on scale anchors—to emotional reaction (e.g., "The research made me think about things I didn't want

[41] Participants encountered different experimental stimuli (i.e., risk-warnings) and compared to Study 1 (Chapter 3), I used a different research participation measure due to resource limitations. Therefore, I interpret these data with caution.

to think about") and perceived drawbacks (e.g., "Participating in this study was inconvenient to me") statements (see exploratory analyses in Supplementary Files at the end of Chapter 10). These data indicate that participants did not report strong negative reactions to analogue trauma research.

Second, participants—on average—reported disagreement or neutrality to "personal benefits" statements (e.g., "I gained insight about my experiences through research participation")[42]. At face value, this finding seems to differ to my Study 1 results, however, recall that I used different reactions to participation measures between studies.[43] As such, the *Perceived Benefits* domain in Study 1 comprised *more items* that were a mixture of personal benefit items and global study benefit items (e.g., I believe this study's results will be useful to others). By comparison, my Study 4 results reflect personally focused benefits, given the subscale name "personal benefit" (e.g., "I found participating beneficial to me"; Newman et al., 2001). In fact, aligning with this idea, in Study 4, participants reported agreement-to-strong agreement, on average, with "global evaluations" statements (e.g., "I think this research is for a good cause"). These statements likely align with *broader*—rather than personal—research benefits. Moreover, the disconnection between the "personal benefits" statements and Study 4 findings fits with differences between encountering an analogue trauma and recalling a personal traumatic experience. For instance, it may be more difficult to derive personal benefit and gain insight into a traumatic experience if not recalling, but rather encountering, one. Therefore, when benefits are separated into personally focused benefits and global evaluations, there are differences in reported benefit for analogue trauma-related research.

[42] Participants' scores were numerically lower, or comparable, to other trauma-related research (DePrince & Chu, 2008; Edwards et al., 2013).
[43] In Study 1, I used the Post-Test Reactions Questionnaire (Yeater et al., 2012) and in Study 2, I used the Reactions to Research Participation Questionnaire (Newman et al., 2001).

Finally, although I note statistically significant differences between trauma-exposed and non-trauma-exposed participants (Supplementary Files), based on scale anchors, both trauma-exposed and non-trauma-exposed participants were between disagree and neutral on perceived benefits, emotional reactions, and perceived drawbacks statements, and between agree-to-strongly agree on global evaluation statements. Hence, these exploratory findings suggest that analogue trauma research conducted with crowdsourced participants—including trauma-exposed participants—may not exceed discomfort definitions (NHMRC, 2023): participants do not report strong emotional reactions or agreement with research drawbacks, and indicate strong agreement with broad research-related benefits. Together, my research indicates that analogue trauma research fits with minimal-risk and discomfort harm definitions—i.e., that the risk and magnitude of harm is no greater than stressors encountered in everyday life, or during performance of routine psychological examinations or tests (BPS, 2021; NHMRC, 2023; Public Welfare Act, 2018).

My research also provides insight into how analogue trauma participation compares to answering trauma-related questionnaires, in terms of risk. Recall in Chapter 2 that I highlighted Carter-Visscher and colleagues' (2007) study as one that uses a paradigm close to analogue trauma exposure (i.e., exposing participants to negatively arousing sounds/images). Participants reported greater distress when answering questions about childhood maltreatment in session one, than when they were exposed to negatively arousing sounds/images in session two. As such, I suggested that analogue trauma exposure might be *less distressing* than answering trauma-related questionnaires. Due to measurement differences, I cannot directly compare my findings in Studies 1 and 4 to Carter-Visscher and colleagues' study. But I can numerically compare my Study 1 findings to Yeater and colleagues' (2012) investigation, and I can numerically compare my Study 4 findings to DePrince and Chu's (2008) work; both these comparison studies involved trauma-related

questionnaires. Opposing my suggestion that analogue trauma participation may be less distressing than questionnaires, participants in Yeater and colleagues' trauma/sex questionnaire condition reported that *everyday stressors* would be worse than participation. Yet, in Study 1, participants exposed to the analogue trauma judged research participation as being somewhere *between* being comparable to everyday stressors and everyday stressors being worse. On average, participants in Yeater and colleagues' trauma/sex questionnaire condition reported numerically greater positive emotion and lower negative emotion, than participants in Study 1. And compared to DePrince and Chu's (2008) work, participants in Study 4 reported numerically greater perceived drawbacks scores, and somewhat comparable emotional reactions scores.[44] These comparisons suggest that analogue trauma exposure is somewhat more distressing than responding to trauma-related questionnaires for participants. However, this slightly more distressing experience is likely short-lived (e,g., Oulton et al., 2018; Rattel et al., 2018; Schultebraucks et al., 2019) and reflects the analogue trauma paradigm's purpose (i.e., to create a temporary dose of symptoms that mimics a trauma response; James et al., 2016).

Summary

Together, my work in Study 1 and 4 (Chapters 3 and 9) runs counter to several IRB concerns regarding psychological trauma-related research conduct. Specifically, my findings oppose the idea that participants experience severe distress or significant emotional reactions, or that *undergraduates* may be uniquely vulnerable to such reactions (Yeater et al., 2012). Overall, my work suggests that analogue trauma research does not exceed minimal-risk research definitions or violate the non-maleficence principle. Put differently, analogue trauma-related research is not as risky as some IRBs and researchers might believe it to be.

[44] Because DePrince and Chu (2008) collected RRPQ responses from participants across four samples (i.e., two undergraduate and two community, where some samples completed questionnaires and some interviews) emotional reactions scores vary (i.e., *M:* 2.56 to 3.17). Hence, my findings are comparable, noting that sample type and participation format varied.

Research Question Two: Do participants—including people with prior trauma exposure—have unique ethical requirements, beyond current ethical guidelines, for participation in psychological research?

There are several ways my research shows that, from the participant perspective, current consent guidelines serve crowdsourced and undergraduate participants (Study 2a and 2b, Chapter 5; e.g., BPS, 2021; NHMRC, 2018; Public Welfare Act, 2018). Again, I draw on exploratory data from Study 4 (Chapter 9) to support this idea. Overall, across crowdsourced and undergraduate samples (Study 2a and 2b; Chapter 5), I found that participants were generally satisfied with current guidelines, that their preferences (e.g., to make consent information more consistent across IRBs) aligned with the current system, and that their existing consent knowledge was low-to-moderate. Trauma-exposed and non-trauma-exposed participants had similar preferences toward consent, particularly for key consent areas (e.g., methods, risks). Further, participants requested changes that reflected exposure to potentially unethical behaviour from IRBs and/or researchers (e.g., inaccurate IRB information provided, participants not receiving responses to inquiries). Thus, my findings also suggest that there is room for improvement when implementing guidelines at the researcher and IRB levels.

My results extend our understanding of the relationship between participants and informed consent in psychological research (Study 2a and 2b, Chapter 5). Although previous research indicates most participants perform poorly on consent-related comprehension tests (e.g., Geier et al., 2021; Perrault & McCullock, 2019)—which creates uncertainty about whether participants are "informed" (e.g., Varnhagen et al., 2005)—my findings suggest that participants are satisfied with the *content* that consent forms should contain. My findings therefore complement existing research that points to improving consent delivery format (e.g., making consent interactive; e.g., Geier et al., 2021), rather than altering the content (e.g., removing consent content; Perrault & Keating, 2018; Perrault & Nazione, 2016).

Moreover, my findings progress understanding about why participants choose not to read and/or skim psychological consent forms (e.g., Knepp, 2014; Perrault & Nazione, 2016; Ripley et al., 2018). One explanation for participants' behaviour is that because they have previously been exposed to psychological consent information, they have substantial basic consent knowledge, and thus, do not need to closely engage with consent. Indeed, previous research investigating why undergraduates do not read consent forms shows 19.8% of participants report they thought the consent form was "same as usual" (i.e., assuming the form would say what they usually say), and 11.2% report they assumed the study was ethical (i.e., "...a study conducted by the university would not harm/penalise me in any way"; Perrault & Keating, 2018). But my findings do not support this explanation and instead, indicate there may be a gap between what people think they know about consent and their *actual* knowledge. Even in Study 2a where participants perceived themselves as *very experienced,* their pre-existing knowledge was not comprehensive.

From a trauma-related research perspective, my findings contribute to understanding about whether trauma-exposed participants want, or warrant, special precautions included in ethical guidelines. Trauma-exposed people who participate in psychological trauma-related research are identified as vulnerable and potentially subject to unique ethical precautions, like universally vulnerable populations are (e.g., Newman et al., 2006; Newman & Kaloupek, 2009). My findings in Study 2a and 2b (Chapter 5) provide evidence against identifying trauma-exposed people in this way: my samples comprised at least two thirds of people reporting trauma-exposure and I found that consent preferences were *similar* irrespective of trauma-exposure status. Additionally, recall that several suggestions for consent guideline improvement were either already addressed in current ethical guidelines, or specific to the sample-type and *unrelated* to prior trauma-exposure (i.e., MTurk worker preferences relating to pay). Hence, I found no evidence that trauma-exposed participants want additional—

special—precautions included in the current consent process. Running counter to the idea that trauma-exposed people are particularly vulnerable, and thus require special precautions in trauma-related research (e.g., Newman et al., 2006), my exploratory results in Study 4 (Chapter 9; see Supplementary Materials at the end of Chapter 10) indicate that trauma-exposed participants did not report strong negative reactions—or distress—to viewing an analogue trauma. My findings therefore support existing discussion that trauma-exposed participants—while requiring safeguards to manage risk during participation (e.g., sufficient debriefing, referral to mental health services)—do not generally meet vulnerable population definitions (Collogan et al., 2004; Newman et al., 2006). Although, my findings reflect trauma-exposure operationalised via Criterion-A for a PTSD diagnosis (APA, 2013), and thus might differ if trauma-exposure is operationalised differently (e.g., participants reporting repeated trauma exposure or high PTS-symptoms might endorse special consent precautions).

Summary

Together, my work indicates that participants in psychological research—including those with previous trauma exposure—do not have unique requirements that extend beyond current ethical guidelines, nor do they report strong emotional reactions to analogue trauma research. Overall, participants were generally satisfied with current guidelines, had low-to-moderate existing knowledge about guidelines, and useful feedback for researchers and IRBs to consider (e.g., greater consistency in applying consent guidelines across research).

Research Question Three: Are informed consent risk-warnings contributing to negative outcomes for participants in psychological trauma-related research?

Across Chapters 7 to 9, I assessed a critical concern researchers have raised: that informed consent risk-warnings may contribute to negative outcomes for participants in psychological trauma-related research (e.g., Abu-Rus et al., 2019; Becker-Blease & Freyd, 2006; Bridgland & Takarangi, 2021). To first assess this concern, I systematically gathered

experimental studies examining risk-warning information delivered during the consent process, and expectancies and/or nocebo effects (Chapter 7). Despite researchers' existing concern and evidence suggesting the informed consent process contributes to nocebo effects (e.g., Amanzio et al., 2009; Colloca, 2024), my scoping review was the first to show that few *empirical* investigations have examined whether consent risk-warnings change expectancies and/or cause nocebo effects ($N = 9$). Such empirical work was near non-existent for psychological-based outcomes—such as distress—or in a trauma-related research context. Overall, my scoping review found mixed evidence that consent risk-warnings change people's expectancies and/or cause nocebo effects. Further, my review identified key research limitations in this area—such as insufficient control conditions—and made methodological design recommendations (e.g., including appropriate control conditions, consistent framing of conditions). I subsequently used these recommendations to design three consent risk-warning experiments (Chapters 8 and 9). I operationalised my experimental investigations using a nocebo effect-type chain; that is, suggested side-effects delivered via risk-warnings attenuate participant's expectancies (i.e., first step), and cause nocebo effects (i.e., second step).

Expectancies

There are two main ways that my research shows that consent risk-warnings do not cause meaningful changes to participants' expectancies—i.e., the first step in the nocebo effect chain. First, when measuring participant expectancies for individual side-effects (e.g., "I expected to feel distressed"), in Study 3a, I found that participants exposed to a high-risk or a negligible risk-warning reported similar expectancies about their reactions to research participation measured post-warning. In Study 3b, when participants encountered either a high-risk, negligible risk or no warning, and reported their expectancies pre- and post-warning, high-risk participants expected to experience more distress and feel more upset than

participants exposed to other warning types. Indeed, when I collapsed the high-risk and negligible risk-warning conditions to form a composite score on expectancy items (e.g., "I expect to feel distressed"), high risk-warning participants had significantly greater negative expectancies regarding warned of side-effects (e.g., distress), relative to the other warning conditions. But this finding was not practically meaningful: participants still tended to *disagree* (i.e., $M \sim 1.5$ to 2.3, where *6 = Strongly agree*) with expecting to experience warned of side-effects, regardless of warning encountered (Study 3a and 3b; Chapter 8). Further, when I measured expectancies generally (i.e., how likely participants think experiencing side-effects would be) to account for warned and unwarned side-effects (e.g., participant-generated side-effects), I replicated the finding that a risk-warning—relative to no warning—did not change expectancies. Like Study 3a, participants disagreed with the idea they would experience side-effects (i.e., endorsing low levels: < 5 on an 11-point scale).

Second, when operationalising expectancies via anticipatory anxiety—contrary to predictions (Bridgland et al., 2023)—*negligible risk* participants reported more anticipatory anxiety after encountering the warning than did high risk-warning participants (Study 3a). However, the idea that these divergent finding might reflect negligible risk participants finding the upcoming participation experience more uncertain or unpredictable than high risk-warning participants was unfounded in Study 3b and Study 4 (Chapters 8 and 9): participants reported similarly low levels of anticipatory anxiety irrespective of warning encountered. That is, based on scale anchors, across Studies 3a, 3b and 4, all participants reported being between *not at all* and *somewhat* anxious. Together then, these findings signal good news for participants, trauma researchers, and IRBs, because informed consent risk-warnings do not contribute appear to negative expectancies in participants.

Overall, my findings are conceptually consistent with Senn and Desmarais' (2006) pattern of findings: that consent risk-warning type *did not* affect participant expectancies for

participation elements (e.g., “What types of questions do you think you will be asked?”; “What type(s) of slides do you think you will be seeing?”) in a study involving sexually explicit materials or questions about sexually coercive experiences. My findings extend Senn and Desmarais’ work in two main ways. First, my work replicates their expectancy findings related to methodology (e.g., examining whether the nature of questionnaires or materials aligned with participant expectations) and extends them to expectancies about people’s own responses. Second, my findings add to their null expectancy findings for different risk-warning types. In both studies, Senn and Desmarais’ warnings (e.g., “These images may be upsetting or objectionable to some people”) contained minimal information about psychological side-effects (e.g., distress), while my risk-warnings contained multiple psychological side-effects (e.g., upset, afraid) and longer-term side-effects (e.g., nightmares).

But my findings are inconsistent with previous trigger warning findings that warnings increase participant expectancies and cause a noxious anticipatory anxiety period between encountering the warning and viewing potentially negative content (Bridgland et al., 2019; 2023; Sanson et al., 2019). My findings therefore add to understanding of risk-warnings for psychological outcomes, indicating that while risk-warnings and trigger warnings may intuitively appear similar, their effects on people are not.

There are at least three reasons why trigger warnings and consent risk-warnings produce different effects. First, relative to consent risk-warnings, the term “trigger warning” may have different sociocultural meanings attached to it (e.g., using trigger warnings makes students feel like their teacher is part of their social clique; Bridgland et al., 2023). Likewise, trigger warnings are political and associated with ongoing debates about whether they work (e.g., George & Hovey, 2020; Kaufman, 2019; Robbins, 2016), whereas consent risk-warnings are not; anecdotally, people do not usually question their use. Second, different warnings might vary in their effects due to their focus: trigger warnings typically focus on

content (although some warnings occasionally warn about side-effects; e.g., Bridgland et al., 2019; Bellet et al., 2018), whereas consent risk-warnings usually focus on potential psychological side-effects or symptoms (e.g., distress). Finally, the informed consent context itself might alter how warnings affect people. Risk-warnings—depending on university/IRB requirements—are usually included amongst other consent information, potentially making the information less salient. Indeed, one criticism of the consent process is consent form length and/or complexity (e.g., Albala et al., 2010). Further, research shows that amending consent forms does not meaningfully increase participants' consent form comprehension (e.g., bolding information; Perrault & Keating, 2018). By contrast, trigger warnings may be easier to identify because they are usually shown individually, are the focal point (see Takarangi et al., 2023 for example), and are so frequent in daily life that they are even recognisable when shortened (i.e., "TW"). Thus, there are several reasons why trigger warnings and consent risk-warnings differentially affect participants, and thus why they should be considered dissimilar.

Nocebo Effects

Turning to the final step in the nocebo effect chain, I considered whether nocebo effects occur for psychological outcomes, specifically in a consent risk-warning context. Recall in Chapter 6, I suggested that the tentative answer was yes. But my findings in Study 4 (Chapter 9) led me to reconsider this answer. Consistent with previous trigger warning research (Bridgland et al., 2023), my findings show that in an analogue trauma research context, participants exposed to a consent risk-warning for an online trauma-related study *do not* experience psychological nocebo effects (e.g., elevated distress). Although my research expands the scant nocebo effect literature on psychological variables (e.g., affect; Geers et al., 2021; Rooney et al., 2024), my findings oppose prior research that finds nocebo effects occur for medical outcomes due to the informed consent process (e.g., Amanzio et al., 2009;

Colloca, 2024; Neukirch & Colagiuri, 2015). Aligning with previous trigger warning research (Bridgland et al., 2023), my findings—or lack thereof—also extend to participants with reported trauma-exposure, including participants whose traumatic exposure was similar to the trauma film's content (Study 4). These results indicate that consent risk-warnings do not differentially affect—either protect or harm—participants reporting prior trauma-exposure. Further, I found that the risk-warning had *some* association, albeit small, with participants' expectancies and subsequent psychological outcomes (e.g., distress); this effect was correlational and was absent when analyses were conducted between-groups. Overall, my findings indicate that consent risk-warnings used in psychological trauma-related research do not cause psychological nocebo effects. Hence, despite existing evidence showing side-effect warnings alter participant expectations (e.g., Elsenbruch et al., 2019), and that expectations are a primary nocebo effect mechanism (e.g., Rooney et al., 2023), my findings (Chapters 8 and 9) do not support either possibility for consent risk-warnings. In sum, consent risk-warnings do not seem "hazardous to health" nor do they create a "self-fulfilling prophecy" (Loftus & Fries, 1979; Loftus & Teitcher, 2019).

My findings (Study 4; Chapter 9) clarify and extend trauma-related risk information findings from Bussell's (2017) doctoral thesis. Recall Bussell investigated whether participants given consent risk information with "harsher language" experienced negative outcomes (i.e., nocebo effect) or responded to trauma-related and psychopathology measures (e.g., depression) differently to participants given consent risk information with "trauma-informed language". Although Bussell found people in the harsher language condition potentially experienced nocebo effects—i.e., via *self-reporting* higher scores on psychological outcome measures than the trauma-informed language condition—this effect was only observed for participants who self-reported via questionnaire and not for those that were interviewed. But Bussell's design did not allow them to determine whether participants

in the harsh language condition had experienced nocebo effects, overreported due to demand effects, or accurately reported because the harsh language helped participants feel comfortable with their report. My research provides evidence against the possibility that participants experienced nocebo effects, at least on self-report measures. Although I did not use interviews, my work suggests that risk language—such as the harsher language example used in Bussell's work—either causes demand effects or accurate symptom reporting, compared to other warning types, such as the warning using trauma-informed language. Future research should determine how risk information influences participant responding (e.g., causing demand effects or accurate reporting compared to other research modalities), particularly on self-report measures used widely in psychological research.

My findings also cast doubt on whether nocebo effects occur without expectancies for psychological side-effects. Recall in Study 3 (Chapter 8), I proposed that participants may not expect to experience warned of side-effects, such as distress, but after exposure to the participation experience, they may feel more distressed than anticipated via a *contrast effect* (Wilson et al., 1989). According to the Affective Expectation Model (Wilson et al., 1989), when a discrepancy occurs between someone's expectations for an experience and the experience itself, they do one of two things, depending on whether they notice the discrepancy. If a person does not notice the discrepancy, they assimilate their reaction toward their expectation (e.g., not feeling distressed). But, if a person notices the discrepancy, they *contrast* their reaction away from their prior expectation (e.g., feeling distressed). Because I found risk-warnings did not cause nocebo effects, and that the risk-warning in Chapter 9 was a high-risk or extreme warning exemplar, it is unlikely that participants experience nocebo effects via contrast effects. Perhaps the discrepancy between previous expectations (Chapter 8, Study 3) and participation experience (Chapter 9) is not noticeable to participants. Thus, they assimilate deviations in their reaction toward their expectations.

My findings in Study 3a and 3b, and Study 4 (Chapters 8 and 9) also have implications for related literatures. Turning first to the suggestion literature, despite prior research indicating that people are highly susceptible to suggestion (e.g., Loftus, 2005; 2017; Loftus & Fries, 1979; 2008; Otgaar et al., 2023; Weingardt & Loftus, 1995), I found no evidence that people are suggestible via the consent process in a trauma-related research context in the same way as they are in other settings (e.g., eyewitness testimony). My findings likely diverge because—unlike this extant literature—I did not explicitly examine autobiographical *memory,* which is malleable and therefore susceptible to suggestion (see reviews by Loftus, 2005; 2017). However, recall that some prior research has found a nocebo-type effect when participants were asked to recall their negative experience 1 (Takarangi & Strange, 2010), or 2 weeks later (Bridgland & Takarangi, 2021). Thus, perhaps suggestion via consent risk-warnings contaminates people's memory as it fades over time, causing a nocebo effect-like reaction.

Second, pilot study findings from my research highlight how affective forecasts (i.e., predictions people make about their future emotions; Gilbert & Wilson, 2009) made about *imagined* scenarios show forecasting biases, relative to real situations. When exploring reasons for my Study 3a findings, and when preparing to conduct Study 3b (Chapter 8), I conducted a pilot study. I asked participants to imagine they were going to participate in a trauma-related study and rate their anticipated emotion attached to that event, using the same scale as in Chapter 8 (see Supplementary Files at the end of Chapter 10 for data). Though the sample is small, and I interpret results with caution, the results pattern indicated that, numerically, participants exposed to the high risk-warning anticipated more negative side-effects (e.g., feeling distress, anxiety, upset, global negative outcomes), compared to participants who encountered the negligible risk-warning. These results were also numerically, on average, greater (~ 3.5 to 4) than when participants *participated* in the study.

Generally, this finding fits with the idea that when making affective forecasts, people typically underestimate their ability to cope (i.e., *immune neglect*; e.g., Hoerger, 2012). Put differently, my research shows when people participate in trauma-related research—compared to when they imagine participating—they tolerate the process more than when imagining (i.e., not expecting to experience warned of side-effects). Although researchers would need to be mindful of contaminating measures, future research could first ask participants to imagine participating in a trauma-related study and complete expectancy measures, then offer them the opportunity to participate and contrast participant expectancies between the two experiences.

Alternative Processes Associated with Trauma-Related Research Participation

My research has implications for our understanding of how participants approach psychological informed consent procedures, and specifically, how participants perceive, process, and cope with trauma-related research. Although these data were gathered incidentally, participants in Study 3a and 3b reported feelings and/or concerns about participation that my quantitative findings did not capture. These responses indicated that some participants engaged in emotion-management strategies (Chapter 8). One general interpretation—since I do not have empirical data that suggests people engaged in these strategies more if they encountered a high risk-warning—is that participation in trauma-related research prompts participants to deploy emotion management strategies. This deployment is a positive sign where ethics is concerned because it suggests some people have appropriate cognitive resources, and apply them, to *cope* with participation.

Another potential interpretation is that the consent risk-warning violated some participants' expectations, leading to emotion management. According to the ViolEx Model, expectation violations change or maintain people's expectations (Rief & Petrie, 2016; Panitz et al., 2021). Possibly, since participants were online—and presumably experienced in

psychological research participation (Study 2; Chapter 5)—they held a *generalised expectation* about how they would react and/or cope with participation. Some participants probably held *situation-specific* expectations about psychological trauma-related research (Pantiz et al., 2021), such as believing they would be okay if they participated (Study 3, Chapter 8). When these participants encountered the risk-warning, the side-effect information may have opposed their expectation, and therefore violated their expectations for participation (i.e., that they might not be okay). To address this mismatch, and prevent expectation update, some participants may have used *cognitive immunisation* (Panitz et al., 2021)—the emotion management strategies participants reported using. Not updating their expectation likely served as an emotional protection mechanism (Panitz et al., 2021). For instance, participants could proceed with participation if they maintained the expectation that they would be okay.

Other participants reported using the consent risk-warning to mentally prepare for participation (Chapter 8); trigger warning advocates make a similar proposal (e.g., Bridgland et al., 2022). Although what constitutes mentally preparing is unclear, previous trigger warning research has operationalised mental preparation as deploying coping strategies, such as reappraisal (Bridgland et al., 2022). This research found that warnings did not prompt people to bring to mind coping strategies, suggesting that warnings may help people *feel* prepared, but this feeling does not transfer to actual preparation (Bridgland et al., 2022; Bridgland et al., 2023). My research supports this idea: in Study 3a, some participants reported engaging in emotional preparation—at similar rates across warning conditions—and in Study 4, I did not find that warnings influenced—or *protected*—people's emotional responses. Thus, in the consent risk-warning context, this preparation feeling may reflect people feeling informed; that is, having risk information makes participants feel knowledgeable and prepared for the future. Overall, future research should explore to what

extent participants use emotion management strategies and whether they are effective, together with how risk-warnings help participants mentally prepare.

Summary

Together, much to IRBs' and trauma researchers' relief, my findings across Chapters 8 and 9 signal that consent risk-warnings are *not* contributing to negative outcomes for participants in psychological trauma-related research. These findings also include trauma-exposed participants.

Theoretical and Conceptual Implications

Need for Psychological Theory

My research provides an opportunity to develop psychological theory that underpins trauma-related research participation and informed consent research. Presently, there is no theoretical model that accounts for: trauma, research ethics, and trauma-related research participation or informed consent as applied to psychological research. Such theoretical development is needed for several reasons. First, it would provide a useful working model for understanding how and/or why participants respond to trauma-related research participation and informed consent procedures as they do. Second, theory would help move researchers away from comparing research findings against vague ethical guidelines that are updated at various increments (e.g., NHMRC guidelines are updated every 5 years). Finally, theoretical development would help guide future research endeavours (e.g., how to better support participants in trauma-related research, how to ensure participants are informed). Below, I discuss elements that might comprise such a model.

Meaning Making. My research has implications for the *meaning making* model (Park, 2022). According to this model, exposure to a traumatic event can violate people's global evaluations (e.g., that the world is fair) and influence their event appraisals (e.g., that the event was unfair or unpredictable), causing distress (Park & Ai, 2006; Park, 2022). One

way to cope with this distress is to make meaning of the situation (e.g., as offering a chance for growth; Park, 2022). In my research, analogue trauma-exposed participants may have made meaning about their participation experience (e.g., my participation might help improve PTSD treatments) to cope with participation, accounting for their reported low-to-moderate negative emotion *and* moderate benefits. Meanwhile, participants who completed cognitive tasks were likely unable to make meaning about participation because their task did not violate their global evaluations or influence event appraisals. Future research should investigate meaning making in trauma-related research participation using specific meaning making measures (see Global Meaning Violations Scale; Park et al., 2016) to ascertain whether, for instance, participants who engage in meaning making are more likely to report a favourable cost-benefit analysis (i.e., where participation benefits significantly outweigh participation costs). If so, researchers could use meaning making to enhance trauma-related research participation (e.g., by providing meaning making instructions during debriefing procedures).

Priming. My research uses and extends prospective priming approaches to a psychological risk-warning context. The methodology I adopted is consistent with prospective priming because participants first encountered the risk-warning—i.e., prime—and responded to measures following the prime (Chapters 8 and 9). That is, rather than participants being exposed to the prime *and* research participation first to understand the relationship between the prime and the target (i.e., retrospective priming; Minton et al., 2017). But my findings indicate that risk-warnings do not prospectively prime participants by causing them to interpret their participation as being more negative, relative to participants who do not encounter the prime. Given prospective priming approaches have been applied in consumer (Minton et al., 2017) and in-lab cognitive research (e.g., Jones, 2012; Neely et al.,

1989) contexts, my work contributes to theoretical understanding of priming in a psychological consent risk-warning context.

Response Expectancy and Nocebo Effects

Although nocebo effects and response expectancy are distinct concepts, there is significant overlap between the two. Recall that extant discussion converges on the nocebo definition that people's *negative expectations* cause negative outcomes (Barsky et al., 2002; Colloca, 2024; Faasse, Helfer et al., 2019; Hahn, 1997). As such, response expectancy is one theory that explains how nocebo effects work and nocebo effects essentially describe the potential *outcome* of expectancy (i.e., the adverse or negative effect). Therefore, my research has conceptual implications for both, which I will discuss together below.

At face value, my research does not support response expectancy theory (Kirsch, 1985; 1997). Overall, my main situational cue (Kirsch, 1997)—consent risk-warnings—did not meaningfully increase people's side-effect expectations or cause participants to experience these side-effects (Chapters 8 and 9). However, it is difficult to determine whether my research does not support response expectancy theory or does not appropriately *test* the theory. According to response expectancy theory, people predict their automatic reactions to situational cues and develop anticipated reactions (Kirsch, 1985). My findings showed that participants did not form side-effect expectancies in the first place and therefore I could not appropriately test whether they then developed anticipated reactions. There are several possibilities for why participants did not form these expectancies.

First, participants in my research were likely experienced trauma-related research participants (Chapter 5) who had encountered different risk-warnings across multiple studies. Hence, it is possible that these participants initially formed strong expectancies about trauma-related research but have had many experiences where risk-warnings did not result in the warned of side-effects—particularly given evidence of the disconnect between the level of

risk information and actual risks of participation across trauma research paradigms (Abu-Rus et al., 2019). Likewise, prior experience and conditioning—i.e., the connection between side-effects and their experience—are important contributors to people's expectations and hence to nocebo effects, particularly for pain-related outcomes (Colloca, 2024; Bagarić et al., 2022; Reicherts et al., 2016; Stewart-Williams & Podd, 2004). Consequently, participants may stop forming strong expectancies altogether, meaning the first step in the response expectancy chain does not exist within this context.

Second, the emotional reactions I investigated differed from the bodily states or sensations prior response expectancy and nocebo effect studies examine (e.g., Bagarić et al., 2022; Colloca, 2024; Kirsch, 1985; 1997; 2016). For instance, previous research has investigated people's pain and itch perception (e.g., Anton & David, 2013; Montgomery & Kirsch, 1997; Rooney et al., 2023; van Laarhoven et al., 2011), alertness attached to supposed caffeine consumption (e.g., Kirsch & Weixel, 1988), and outcomes (e.g., aggression) associated with alcohol consumption (e.g., Assefi & Garry, 2003; Hull & Bond, 1986; Kirsch, 1985). But participation in trauma-related research and associated risk-warnings do not typically have a bodily state or sensation attached—such as perceived pain or alertness.

Rather, trauma research outcomes are generally related to more abstract emotional states, such as anxiety or feelings of distress. Perhaps then psychological outcomes are more difficult for people to make judgments about, relative to bodily or sensation-based—i.e., more objective—outcomes. We know from the affective forecasting (i.e., predictions people make about their future emotions; Gilbert & Wilson, 2009) literature that people have difficulties predicting their future emotions, particularly for negative events (e.g., Wilson & Gilbert, 2005). Hence, people may not develop strong negative expectancies about emotional or psychological side-effects, compared to bodily or sensation-based outcomes (e.g., pain, nausea). Alternatively, in a psychological consent context, side-effect types and/or

suggestions made might be less potent than for bodily or sensation-based outcomes (i.e., medical). For example, people may perceive psychological side-effects, such as distress, as less serious or long-lasting—due to their transient nature—compared to physiological side-effects, such as headaches. Therefore, my research indicates that response expectancy theory may better account for bodily or sensation-based outcomes, than abstract emotional reactions. Indeed, Coteţ and David (2016) have proposed a revised response expectancy model whereby affective forecasts are a subset of response expectancies; that is, the relationship between affective *predictions* (e.g., response expectancies and affective forecasts) and affective *outcomes.*

Although I did not measure bodily states or sensations here (Chapters 8 and 9), potentially consent risk-warnings delivered in trauma-related research *might* have a bodily state or sensation attached to them that is amenable to changes in expectancies—and subsequent nocebo effect measures. For example, perhaps trauma-related participation has anxiety-related physical indicators—such as increases in heart rate. Supporting this notion, one study found that viewing a trigger warning increased participant's heart rate, respiration rate, and skin conductance, more than participants who viewed a content warning (e.g., PG-13) or control stimuli (Bruce et al., 2023). That is, they found a nocebo effect for the phrase "trigger warning". Since we know that anxiety has physiological markers, as in other psychophysiological research investigating anxiety (e.g., Hyde et al., 2019; Lee et al., 2011), perhaps response expectancies and nocebo effects for psychological side-effects are better captured using psychophysiological measures, such as heart rate. Alternatively, perhaps warning people about these stress markers (e.g., "you may experience an increase in heart rate") would manifest such negative outcomes. Though, I note this warning type is likely atypical in trauma-related research.

Third, the *treatment context* of participating in analogue trauma research differs to the context in response expectancy and nocebo work (e.g., Colloca, 2024; Faasse, Helfer et al., 2019; Kirsch, 1985; 1997; Rooney et al., 2023). I conceptualised trauma-related research participation—i.e., viewing the trauma film—as the *treatment* participants were exposed to. This procedure probably differs to traditional medical-based treatments and their associated context (e.g., taking pain medication to relieve a headache); the ritual of "sickness" (Hahn, 1997). Additionally, participants may not actually *perceive* psychological research procedures, such as the trauma film paradigm, as a treatment, suggesting that response expectancies and nocebo effects are likely only attached to traditionally recognised treatments rather than psychological research procedures.

Fourth, and relatedly, the "situational cues" that participants encountered in my work are notably different to previous response expectancy and nocebo effect research (e.g., Bagarić et al., 2022; Colloca, 2024; Kirsch, 1985; 1997). Because data collection occurred online, participants had minimal-to-no interaction with the researcher and were presumably completing the study in familiar surroundings (e.g., not in-lab). Hence, they did not encounter *multiple* situational cues that potentially interacted and contributed to their expectancy uptake. For instance, perhaps if a seemingly clinical researcher (e.g., wearing a white coat, seemingly cold or unempathetic demeanour), in a lab setting (e.g., waiting room, uninviting data collection room with blank walls) explained consent information to participants, these factors would interact with the suggested side-effects to cause such adverse outcomes (e.g., by making the side-effects seem more plausible; see also Colloca, 2024 for factors that contribute to nocebo effects). Indeed, prior placebo work has enhanced people's expectancies associated with alcohol and medication by using situational cues—e.g., weighing participants, pouring inert alcohol from vodka bottles, submerging glasses in vodka to make them smell like alcohol, preparing substances in plain view—to make them believe they

consumed alcohol or cognitive-enhancing medication (e.g., Assefi & Garry, 2003; Clifasefi et al., 2006; Clifasefi et al., 2007). However, recall online participants exposed to side-effect information (e.g., headaches) about low frequency noise—who then *encountered* low frequency noise—reported more side-effects than participants exposed to no side-effect information (i.e., nocebo effects; Barnes et al., 2023). This finding opposes the idea that participants' expectancies did not differ due to situational cues associated with an online context.

Thus, an alternative suggestion relates to the nocebo vehicle: compared to prior nocebo effect research that uses objective or tangible vehicles, such as low frequency noise, pain stimuli, or inactive pills, participation experience in trauma-related research is not tangible or time-limited. This explanation parallels differences in findings with the trigger warning literature, where warnings typically centre on *content* (i.e., tangible) and subsequent reactions to content (e.g., distress). Therefore, for psychological side-effects, the *treatment context*—including what people recognise as a treatment—and *combination* of situational cues may be important in changing participants' expectancies.

Finally, there may be different cultural associations with informed consent—or risks—in psychological research, compared to other outcomes. For example, informed consent has long been associated with medical research (e.g., Boulton & Parker, 2007), and the risks that such research carries (e.g., medication side-effects in clinical trials; see also Hahn, 1997). In fact, social scientists argue against our field's inclusion in the biomedical ethics framework (i.e., the framework psychological research currently operates under) because, for instance, informed consent—as currently implemented—might not be appropriate to our work (Boulton & Parker, 2007). Further, people's most common informed consent experiences are most likely within the medical treatment context (e.g., the ritual of informed consent prior to treatment). People may also associate informed consent and

research risk with previous medical ethics violations, such as the atrocities observed in World War II or the Tuskegee Syphilis Study (e.g., Arras, 2008; Corbie-Smith, 1999). Although psychological research is likely associated with ethical violations, such as the Stanford Prison Experiment, the extent of this association possibly differs to that of medical research. Hence, different cultural associations between informed consent, and medical and psychological research risk, may explain why participants did not form expectancies in the psychological trauma-related research context.

Bayesian Theory

My work adopted Ongaro and Kaptchuk's (2019) Bayesian approach to nocebo effects. Indeed, Kirsch (2018) has also highlighted the "close affinity between expectancy theory and Bayesian predictive coding formulations, in which brains are described as 'prediction machines'" (pp. 83-84). Although this approach accounts for placebo and nocebo effects, and perceived symptoms (e.g., pain), my research suggests this approach may also apply to psychological nocebo effect-type research (Chapter 9). I suggested that the consent risk-warning (i.e., external input) may have heightened people's sensitivity to negative feelings, causing them to re-evaluate their reactions and update their prior. One point that is vague in my hypothesising is how people update their priors about *emotions,* relative to somatic symptoms, such as pain, that people can sense. That is, from a Bayesian perspective, how do people appraise how they feel and decide when this changes? One paper—considering predictive coding (i.e., a similar predictive model to Bayesian approach)—suggests that interoception and perception may work together to inform emotion—or a person's inferred state (Seth, 2013). For example, Seth suggests within a larger model that emotional reactions may be informed by "continually-updated predictions of the causes of interoceptive input" (p. 568). However, further work is needed to consider how Bayesian theory may account for psychological nocebo effects, such as distress.

Methodological Implications

Informed Consent (and Demand) Effects on Psychological Research

My research highlights that researchers—particularly in sensitive research areas (e.g., trauma-related, sexual-related)—should consider potential demand characteristics associated with informed consent procedures. Other researchers have raised concerns over demand caused by consent procedures, including how questionnaires are administered (e.g., interview or self-report) and how experimental stimuli are evaluated (e.g., sexual-based images as more negative; Bussell, 2017; Senn & Desmarais, 2006). My findings also indicated that demand was present (Study 3a and 3b; Chapter 8): participants who wanted to be "good participants" appeared to underreport their negative expectancies (e.g., Orne, 2017). Though these findings are correlational—and should be interpreted with caution—they suggest that participants responded in ways aligning with their participation goal (e.g., coping with trauma-related research participation). This responding also highlights a worrying possibility: participants may have suppressed their negative emotions to successfully participate. Indeed, prior research indicates that greater engagement in suppression is negatively associated with well-being (e.g., more depressive symptoms) and interpersonal function (e.g., less likely to share negative/positive emotion with others; Gross & John, 2003). Although there is no easy answer to balancing demand risk against informed consent needs (e.g., providing participants with adequate study information), researchers should first consider how the information they provide during consent impacts their results. One strategy might be to include a social desirability or demand-type measure—as I did here—within the research design. Alternatively, in line with open science practice principles, researchers could share their consent materials in full. Doing so may help with cross-study comparisons and identifying, for instance, why effects are present/not present or stronger/weaker between studies.

Measuring Expectancy

My research supports Faasse's (2019) call for nocebo effect researchers to measure participant expectancies in experimental work. Instead, because some researchers administer a manipulation that tries to alter participants' expectancies, they assume negative expectations cause observed changes without direct measurement (Rooney et al., 2023). Indeed, Rooney and colleagues (2023) identified 28 nocebo effect studies—out of 59 studies meeting inclusion criteria—that measured expectancies; of their sample, 68% of included studies were about pain. Therefore, given extant nocebo literature focuses on pain and that it is unclear whether affective outcomes respond to response expectancy, it is important that researchers *measure* participant expectancies, particularly for different outcomes.

Relatedly, when measuring participant expectancies for emotional outcomes in warning settings, as in Studies 3a, 3b and 4, researchers should consider using specific *and* generalised expectancy measures. Specific emotion-based expectancy measures have the advantage of directly mapping onto warned of side-effects and thus informing us about the warning's *direct* effect, but using such measures may present statistical challenges (e.g. Type I error; Study 3a and 3b). By contrast, measuring generalised expectancies may overcome this limitation and additionally, capture side-effects that participants were not warned of, but may have an expectancy about experiencing (e.g., feeling disgusted). Hence, researchers should weigh the benefits and costs to how they measure expectancies associated with consent risk-warnings.

Acclimatisation Period in Psychological Research

For researchers interested in measuring emotion or mood—particularly in pre-to-post study designs—my work suggests that implementing a research acclimatisation period/task when participants begin participation may be beneficial. When I measured participant's anticipatory anxiety *prior* to informed consent, I found that participant's baseline anxiety varied (Study 3b; Chapter 8). An example task that may help participants adjust to research

participation include incorporating an acclimation/waiting period. This idea comes from the acclimation/waiting period used when administering the Trier Social Stress Test that aims to minimise elevated cortisol levels upon first measurement (Labuschagne et al., 2019); a proxy for stress measurement. Alternatively, researchers could show participants a relaxing video when participation starts.

Considerations for Conducting Warning Research

My research has implications for how researchers investigate informed consent risk-warnings, and warnings more generally. When considering study design, there are several strategies researchers can use to maximise their study's internal validity. First, researchers should closely consider how they construct their warning conditions. For instance, between conditions, wording should differ on one aspect (e.g., positively/negatively framed symptoms) and length should be similar. Second, if possible, researchers should use a no warning control condition to compare to their warning condition(s). In trauma-related consent warning research, it is difficult—ethically—to have a true no warning condition, therefore researchers should use a no side-effect warning condition. Third, researchers should consider how to ensure participants *view* the consent risk-warning, while maximising ecological validity. Potential methods include: asking participants to recall the warning at the end of the study, using an audio warning version that participants listen to, holding participants on the survey page that contains the consent risk-warning, and/or asking participants to initial next to the warning. These suggestions have unique limitations, but researchers should consider which method maximises answering their research question and ecological validity, and minimises confounds or data collection challenges (e.g., asking people to recall the risk-warning may mean higher exclusion rates because people incorrectly remember the warning). Finally, the consent risk-warning should be placed within consent information, during consent, rather than later. Indeed, my work shows that having the consent risk-warning within

the consent process yields different effects to having the risk-warning within the study (Bridgland et al., 2023).

Practical and Clinical Implications

Better Support for IRBs

My research highlights the need to support IRBs in their risk judgment process. My findings, alongside prior work (e.g., Jaffe et al., 2015), challenge well-intentioned concerns that some IRBs hold about trauma-related research conduct, such as that participation may cause severe distress in undergraduate participants and that trauma-related research is riskier than other psychological research types (Chapter 3; Yeater et al., 2012). Although such evidence is helpful to IRBs in evaluating trauma-related research risks, this evidence is only helpful if communicated to IRBs.

There are several ways to disseminate relevant findings to IRBs. First, trauma researchers should consider joining their IRB to directly provide trauma-related research expertise (Newman, 2008). Second, in research proposals undergoing IRB review, researchers should outline findings from the trauma-related research participation literature to help guide IRB decision making. For example, if conducting research with undergraduate students, the applicant could include prior research that suggests the minimal risk associated with trauma-related research in this population. Indeed, the Australian *National Statement on Ethical Conduct in Human Research* (2023) states that when assessing risk, "...judgments should be based on the available evidence. The evidence may be quantitative, qualitative, or both". To help IRB decision making, researchers should incorporate trauma-related research evidence about risk of harm into their proposals (e.g., Smith & Anderson, 2022). Finally, trauma researchers could develop an educational module for IRB members outlining findings from the trauma-related research participation literature. This module could be in guidebook or video format to ensure easy access to content. IRB members could then use this knowledge

(e.g., that participants typically tolerate participation well) to guide their risk review and decision-making process.

Increasing the Evidence Base

Although there was substantial work conducted in the early 2000s (e.g., DePrince & Freyd, 2006; Griffin et al., 2003; Jaffe et al., 2015; Newman & Kaloupek, 2004; Newman et al., 2006; 2009; Yeater et al., 2012), published research that empirically examines ethical issues facing trauma-related research has markedly dropped off in the last 5 years (see Chapter 2 for relevant literature review). Moreover, despite this research occurring, anecdotally speaking, apprehensions about trauma-related research conduct continue to circulate amongst researchers and some IRBs. Indeed, during my candidature, the Australian research guidelines were updated to add "retraumatisation" under examples for potential risk of harm occurring in research. This addition suggests that expanding the trauma-related research base is needed to change the narrative that trauma-related research is inherently harmful or risky. There are several ways trauma researchers might expand the existing evidence base.

First, although I investigated how undergraduate participants react to participation in analogue trauma film research, it is unclear whether these findings are similar for other analogue trauma types. For instance, prior research shows that participants have different emotional responses (e.g., disgust), depending on trauma film theme (e.g., sexual, traffic accident; Arnaudova et al., 2017). We also know that analogue trauma paradigms are presented differently, both in terms of modality (e.g., on a computer screen, via virtual reality, images rather than film) and perspective (e.g., first-person, third person; e.g., Cuperus et al., 2017; Oulton & Takarangi, 2018). Potentially, these analogue trauma differences alter how participants evaluate their research participation experience (e.g., as being worse than everyday stressors).

Second, and relatedly, future research should determine whether my findings hold for people with particular characteristics (e.g., PTSD symptomology, other psychopathology). Some research indicates that trait anxiety and negative affect predict nocebo effects, and there is some evidence, albeit mixed, that state anxiety is positively associated with nocebo effects (Geers et al., 2021). Recall also that participants with PTSD symptoms who participated in trauma-related research evaluated the experience as somewhat more distressing (Jaffe et al., 2015); although this finding is not explicitly connected to the research experience itself and might reflect people's existing symptoms. Thus, participants reporting more severe psychopathology—probably meaning greater negative affect and distress—might evaluate viewing an analogue trauma differently (i.e., more negatively) or be more susceptible to suggested side-effects via risk-warnings.

Third, all researchers should consider incorporating the Normal Life Stressors scale (i.e., compares participation experience to everyday stressors)—or a similar scale—into their projects. Using this scale in trauma-related research will provide a practically meaningful anchor for participants, researchers, and IRBs to make risk-related judgments within the context of ethical guidelines. For example, having participants compare their participation experience against everyday stressor examples helps inform how distressing participation is, relative to other measurable experiences. Further, including this measure in research types other than psychological trauma research will help researchers and IRBs gain a greater understanding about how risky or distressing *trauma* research is compared to other research types that may not be perceived in the same way (e.g., working memory research).

Further, trauma researchers should share their risk-management protocols. In most psychology journals, researchers must report ethical approval and participant consent procedures. Together with word count requirements, there is often little room for trauma researchers to expand on the risk-management protocols they implemented during data

collection. But we can bridge this gap in understanding between researchers by sharing our materials, data, and risk-management strategies (e.g., having a distress protocol for participants to follow if conducting research online, how consent forms are written). While these risk-management strategies should be empirically tested, sharing strategies amongst researchers is one way to immediately improve how trauma-related research is conducted. For instance, more experienced trauma researchers may have effective risk-management strategies—both in managing risk for participants and satisfying IRB review processes—that other researchers could consider when designing their own trauma research studies.

It is also important that trauma researchers ensure the trauma-research participation evidence base is translated to relevant stakeholders and policymakers. Despite several trauma researchers compiling evidence on whether participant reactions fit with ideas of retraumatisation/harm (Jaffe et al., 2015; Newman, 2008; Legerski et al., 2010), this research is not applied in the recent Australian research guideline update. Hence, we need to consider how to better disseminate this research to different stakeholders (e.g., participants, IRBs, institutions, policymakers). Although there is no easy solution, a recent systematic review regarding dissemination strategies to United States policymakers indicated that "…dissemination is most effective when it starts early, galvanises support…considers contextual factors, is timely, relevant, and accessible, and knows the players and process" (Ashcraft et al., 2020, p. 1). Therefore, trauma researchers should consider how to improve trauma-related research participation research dissemination.

Incorporating the Participants' Voice

My research has implications for respecting participants and supporting their autonomy in trauma-related research. At multiple levels (e.g., policy, IRB evaluation, research design), participant voices should be incorporated into the discussion about ethical challenges facing trauma-related research. As my findings indicated, stakeholders in

psychological trauma-related research (e.g., IRBs, researchers) have views on these issues, but these views may not wholly align with participant views (Chapter 5). Moreover, most research (see Chapter 4)—even my own to an extent—indirectly presents participant views on such ethical issues. Therefore, participants should have an active role in addressing challenges facing trauma-related research participation. For example, when updating guidelines, policy makers could create focus groups with these participants to receive direct feedback. Likewise, IRBs and trauma researchers could hold similar focus groups that allow participants to provide feedback on research they have participated in, reflecting a co-design approach to future research. These feedback platforms would also allow participants to raise concerns that policymakers, IRBs, or trauma researchers have not considered.

Conducting Experimental Trauma-Related Research

My work has implications for trauma-related research conducted online, such as exposing participants to trauma films. Some prior trauma-related research has discussed how to implement trauma-informed models within organisations (e.g., Dawson et al., 2021), or specifically within sexual violence research (Campbell et al., 2019). But these recommendations are not always suitable to online, experimental trauma-related research. For example, applying the trauma-informed principle, "Emphasize survivors' strengths, highlighting adaptations over symptoms and resilience over pathology" to sexual violence research is described as using "active listening techniques during interviews to demonstrate empathy for survivors' feelings and choices" (Campbell et al., 2019). My research outlines several ways that researchers can conduct analogue trauma-related research online in ways that support ethical principles (Chapters 5, 8 and 9). Likewise, my research helps inform online research platform guidelines that researchers may rely on (e.g., Prolific). To show *respect* for participants and support their *autonomy* prior to entering the study, analogue trauma studies should be signposted with an explicit/sensitive content tag and procedural

information described in the study description (e.g., viewing a film that depicts rape). To minimise demand effects, procedural information should focus on *what* participants will do or view, rather than how they might feel. To further show respect to participants, researchers should include appropriate informed consent information (e.g., study purpose, procedure, voluntary participation, benefits and risks, confidentiality, contact information); this information may be personalised to participants on crowdsourced platforms, based on their preferences (Chapter 5). To further support respect, autonomy, and beneficence principles, researchers should remind participants prior to, and when viewing sensitive content, that they can withdraw from participation at any point; include referrals to services (e.g., hotlines) throughout (e.g., at the bottom of the page); provide appropriate debriefing information (e.g., service referrals, researcher's contact details); and participants should complete a mood repair activity (e.g., recalling an event that made them feel proud). Together, my research serves as an example to other researchers and platforms for how to conduct analogue trauma-related research online.

Using Consent Risk-Warnings in Trauma-Related Research

My work also has implications for how researchers, IRBs, and some clinicians use consent risk-warnings in trauma-related contexts. My expectancy-related findings (Chapters 8 and 9) were the first to highlight that consent risk-warnings may not work as intended. While risk-warnings support the informed consent process (e.g., NHMRC, 2023), they also contribute to risk mitigation strategies in trauma-related research. For instance, providing participants with potential risks or side-effects, alongside withdrawal information, helps manage risk associated with trauma-related research. But my findings in Chapter 8 (Study 3a and 3b) showed that participants disagreed that they expected to experience psychological side-effects. If risk-warnings were working as intended, we would expect at least some participants to form stronger expectancies post-warning. My findings also provided evidence

against the idea that risk-warnings help people decide not to participate; over 500 participants consented—and participated—regardless of warning encountered (Study 3a and 3b; Chapter 8).

One argument against this reasoning is that consent risk-warnings also serve to *inform* participants about potential risks—or side-effects (e.g., NHMRC, 2023). However, recall previous research finds the information contained in trauma-related consent forms may overstate risks associated with participation (Abu-Rus et al., 2019). Thus, it is unlikely the risk information some participants are exposed to reflects how most people react to trauma-related research participation (e.g., Jaffe et al., 2015). Consequently, risk-warnings may not *accurately* represent risks associated with participation in trauma-related research, meaning participants are not informed. Together, my findings question how effective consent risk-warnings are, beyond being an institutional requirement (Loftus & Fries, 2008). Therefore, IRBs and researchers should re-consider how consent risk-warnings are constructed and applied in research.

Such consideration could take several forms. First, researchers should investigate alternative risk information presentation options, including interactive consent delivery (e.g., video for online consent information, holding the consent process as a conversation) methods (e.g., Geier et al., 2021). Indeed, in the medical-based nocebo literature, some researchers have proposed alternative risk presentation options that aim to minimise nocebo-type responding (e.g., Faasse Huynh et al., 2019). These options include informing participants about what the nocebo effect is and how it may influence their treatment—or experience—which has been shown to decrease nocebo effects (Crichton & Petrie, 2015). Another presentation option involves using framing effects to alter information, side-effect, or likelihood framing (e.g., “10% of people will develop a headache, 90% of people will not develop a headache”; e.g., Faasse, Huynh et al., 2019; Tversky & Kahneman, 1981).

Therefore, researchers should empirically examine whether risk information solutions proposed in the medical literature can also be applied to psychological trauma-related research to minimise potential adverse outcomes for participants.

Second, risk information in consent forms should reflect psychological trauma-related research's *actual* risk, rather than concerns about trauma-related research (e.g., Abu-Rus et al., 2019; Jaffe et al., 2015; Yeater et al., 2012). For example, researchers could show the following warning if conducting research using the analogue trauma paradigm with an undergraduate sample, "There is no more risk attached to participating in this research study than everyday stressors (e.g., cavity drilled at the dentist) you might encounter. Previous research showed when undergraduate participants viewed a similar trauma film, they experienced some negative emotion during participation, but judged that participation was not worse than everyday stressors". Certainly, such risk information should be accompanied by support services (e.g., mental health services/hotline numbers). Further, consent information should include that participants in psychological trauma-related research often cite personal benefits to participation (e.g., Becker-Blease & Freyd, 2006). Although I acknowledge that including or emphasising benefit information *alone* may be viewed as coercive, including benefits shows respect for participants by providing them with a *balanced* view of benefits and risks.

Third, supporting the ethical principle of *justice* (NHMRC, 2023), researchers and IRBs should avoid warning participants with certain characteristics (e.g., trauma exposure, PTSD diagnosis, people prone to experiencing anxiety) *against* participating in trauma-related research. I make this suggestion based on two lines of reasoning. First, I found evidence that participants responded in ways consistent with demand: participants higher in social desirability appeared to underreport their expectancies, rather than adopting the suggestions from the consent risk-warning (Study 3a and 3b). Because participants believed

they were *participating* in a trauma-related study, these findings potentially indicate that participants underreported their expectancies to appease researchers and align with their decision to participate. Hence, including additional warning information that refers to certain participant characteristics may inadvertently encourage them to respond in ways consistent with researcher goals (e.g., to participate if they will not become distressed), rather than how they feel. For example, perhaps a participant with PTSD sees value in disclosing their previous traumatic exposure even if it means they are emotional during participation (e.g., feeling emotionally heightened when discussing their traumatic event; see Griffin et al., 2003). If this participant feels they need to suppress these emotions to align with research requirements, they may not be appropriately supported during participation (e.g., checking in with researchers, pausing participation or even withdrawing). Second, such warnings work against *autonomy.* It is safe to say that during traumatic event exposure, people's autonomy is violated (e.g., Jaffe et al., 2015). Hence, warning against people with certain trauma-related characteristics to avoid participation does not align with supporting or empowering their autonomy. Rather, we assume we know more about the participant than they do.

Consent Needs for Crowdsourced and Undergraduate Participants

My findings have implications for researchers and IRBs regarding informed consent practices for crowdsourced and undergraduate participants. My research indicates that crowdsourced and undergraduate participants want similar consent information, comprising key consent topics, such as risk information, confidentiality, and participant rights (e.g., withdrawal from participation; Chapter 5). However, crowdsourced participants had unique consent preferences related to compensation and accuracy in method information (e.g., completion times; Study 2a). By contrast, undergraduate participants wanted all potential risks associated with studies listed (Study 2b). Hence, to further show respect for participants,

researchers and IRBs should consider incorporating these participant preferences into consent when working with these specific samples.

My work also suggested that some researchers and/or IRBs were not adhering to ethical practice for informed consent (Study 2a; Chapter 5). These findings remind researchers and some IRBs to prioritise respect for participants, and ensure engagement with ethics (e.g., provide accurate contact information). Moreover, my findings indicate that researchers and IRBs may benefit from consistently incorporating research project reviews and/or audits. For instance, IRB members or people associated with the institution could spot check consent procedures in a similar way to mystery shoppers: they could act as a participant to procedurally check how informed consent is implemented and whether it aligns with ethical procedure.

Informed Consent in Psychology

My work suggests further research on consent is needed, particularly in sensitive research areas. We continue to knowingly use a flawed consent method. For instance, we know that participants often decide to skim or not read consent forms (e.g., Geier et al., 2021), which raises questions about whether participants are truly "informed" (Varnhagen et al., 2005). Some psychological researchers have examined participants' consent experience, including why they choose not to engage with the consent process (e.g., Douglas et al., 2021; Perrault & Nazione, 2016), and within specific psychological research areas (e.g., whether minors can consent; e.g., Kuther & Posada, 2004). But searching for "consent" in top psychology journals suggests "…that consent is indeed not a core topic of study in mainstream psychology…" (Bohns, 2022, p. 1094). This result is ironic considering informed consent contributes to most—if not all—psychological research studies. Hence, to improve consent processes—for both participants and researchers—we need to ascertain how people

subjectively understand and experience consent (Bohns, 2022). In other words, what factors contribute to people feeling as though they have consented in an informed way?

Ethical Guidelines

My research supports the idea that ethical guidelines and harm definitions should be clearly defined. Although ethical guidelines are vague to support interpretation across ethical proposals, this strategy is likely unhelpful to IRBs when assessing a psychological research topic that is subjective and associated with stereotypes (i.e., about trauma-exposed people; e.g., Clapp et al., 2023; Haggerty, 2004; McNally, 2003). Ethical guideline authors explain that research guidelines are not meant to be exhaustive, and instead, refer people to specialised guidelines (e.g., written by industry bodies) that align with federal statements (NHMRC, 2023). However, specialised guidelines within trauma research (i.e., American Psychological Association and the International Society for Traumatic Stress Studies [ISTSS] guidelines), are also vague. For instance, they refer to maximising risk and maximising benefit, with little-to-no reference to existing trauma-related research participation literature (ISTSS, 2024). Minimal specification means it is difficult for researchers to design trauma-related studies and for IRB members to evaluate risk associated with such studies (e.g., whether a participation experience aligns with minimal-risk standards). Specialised guidelines should be expanded to include ethical information specific to trauma-related research. For instance, such guidelines could outline recommendations or examples for: constructing risk information with different trauma research designs, referral services to include in consent and debriefing procedures (e.g., hotline numbers), and which researchers are most appropriate to undertake research with certain populations and study designs (e.g., only researchers with appropriate training should interview trauma survivors about their experiences). Including such detail in specialised guidelines will promote consistency and confidence in trauma-related practices across researchers.

Limitations and Future Directions

Population Type

One limitation of my work is that I did not assess a clinical population (e.g., diagnosed with PTSD, depression, anxiety). Potentially, participants with a clinical diagnosis differ in how they respond to an analogue trauma or to consent risk-warnings, or in their preferences for informed consent. Indeed, we know from previous research that people with PTSD tend to report higher distress, compared to people without PTSD, when participating in trauma-related research (Jaffe et al., 2015); though this finding is not explicitly connected to the research experience itself. Moreover, participants' "trauma-related symptoms" are associated with lower benefits, relative to costs reports (DePrince & Chu, 2008, p. 41). To investigate whether my findings extend to clinical populations, future research should specifically recruit participants with a clinical diagnosis (e.g., via clinic interview) and invite them to participate in analogue trauma research using appropriate risk-management strategies (e.g., informed consent, risk information based on previous trauma-related research involving people with PTSD).

Relatedly, but on a different note, my research comprised Western, Industrialised, Rich, and Democratic (WEIRD; Henrich et al., 2010) populations. As such, my findings are confined to this sample, particularly when coupled with the idea that my research took a Western approach to operationalising ethics and informed consent (e.g., Johnston, 2010; Levine, 1991; NHMRC, 2023; Public Welfare Act, 2018; West-McGruer, 2020). Prior research conducted in the US found diverging results for people who identified as being part of a racial or ethnic minority group: minority status was associated with greater perceived benefits but lower participation evaluations (e.g., liking the idea of contributing to science; RRPQ) when responding to trauma-related questionnaires (DePrince & Chu, 2008). Hence, given different cultural attachments to ethics and consent notions (e.g., McGrath & Phillips,

2008; West-McGruer, 2020), it is likely my findings would differ for non-WEIRD populations.

Research Experience Type

My work primarily involved collecting data from participants online. Potentially, my findings would differ for data collected in-lab. For example, the psychosocial context—or situational cues (e.g., researcher/practitioner's perceived warmth; e.g., Barnes et al., 2024) may interact to change how participants react to consent information (Colloca, 2024)—including risk information—and trauma research participation. While my online collection approach helped control these extraneous variables—or psychosocial factors—the approach also limits the generalisability of my findings to other data collection contexts. Similarly, in-lab or in-clinic data collection may have different environmental elements (e.g., practitioner warmth, perceived credibility) that interact with the research experience, causing findings to deviate from my work here.

Individual Differences

I also did not comprehensively assess individual difference characteristics. I focussed on previous trauma-exposure, which did not influence my findings. In a trauma-related research narrative review, the authors indicate that that how people appraise their ability to cope may play a role in the few participants that report unexpected emotion (e.g., upset; (Newman et al., 2006). Further, extant nocebo effect research suggests "nocebo responders"—people that respond negatively to suggestions, for instance—are characterised by greater catastrophising, emotional distress, and anxiety (Colloca et al., 2020; Colloca, 2024; Kern et al., 2020); although evidence is unclear regarding what characteristics consistently predict a nocebo responder (Kern et al., 2020). Therefore, it would be useful for future trauma-related research participation research to measure individual characteristics,

such as people's perceived ability to cope, to see whether participant reactions to research or risk-warnings differ.

Reactions Over Time

My thesis work is limited to participant responses over a short period (i.e., ~ 10 minutes to ~ 30 minutes). I did not measure whether participants' reactions to trauma-related research participation improved or worsened over time (e.g., greater distress one-week post-participation). Potentially, after participants have time to reflect on their experience and make more meaning (e.g., Park, 2022), their cost-benefit judgments might be greater (e.g., benefits outweighing costs significantly more so than toward the end of participation). Alternatively, perhaps consent risk-warnings act as a source of misinformation or feedback to participants, causing them to remember participating as being more negative one week later (e.g., that they were more distressed; e.g., Bridgland & Takarangi, 2021; Takarangi & Strange, 2010). Future research should address the possibility that reactions to analogue research participation and consent risk-warnings may change over time (e.g., 1 week after participation).

Risk-Warning Paradigm

Further, my findings are limited to the consent risk-warning types and audio clips that I used. Depending on individual IRB requirements, consent risk-warnings likely differ in their construction both between IRBs and between countries (i.e., Australia, US, UK). Additionally, I used an audio clip to ensure all participants were exposed to the consent risk-warning. Given we know people tend to skim and/or not read psychological consent forms (i.e., findings not specific to trauma-related research; e.g., Geier et al., 2021), it was important from an experimental design perspective to control for the possibility that participant might not have encountered the risk-warning. However, this procedure differed to typical online consent procedures where participants are asked to read the consent form. Possibly, my findings would differ for alternative consent risk-warnings (e.g., less side-

effects for people to attend to, risk-warnings about side-effects associated with recalling autobiographical experiences) and study designs that do not use an audio clip.

A final limitation is related to the trauma research context I examined nocebo effects in. Here, all participants were exposed to an *active* treatment because there is no inert or inactive trauma film version. Such films are inherently distressing to participants (e.g., Arnaudova et al., 2017; Holmes et al., 2008; James et al., 2016). Consequently, my research was designed in such a way that both conditions were exposed to an active treatment, rather than one condition receiving an inert treatment. Although I minimised this limitation by using different side-effect warnings between conditions, perhaps I did not observe negative outcomes caused by the consent risk-warning because they were masked by the active treatment. However, even if differences were masked by the active treatment, these differences were likely small and therefore not meaningful. Nevertheless, one method that may be more akin to an inert treatment is to expose participants to the consent risk-warning using a neutral stimulus (e.g., neutrally valenced film, non-sensitive participation context). But this method may cause new challenges, such as contrast effects (e.g., where people contrast their reaction away from their prior expectation; Wilson et al., 1989).

Conclusion

Overall, my thesis aimed to extend understanding of ethical issues facing psychological trauma-related research by focussing on three concerns. First, I examined how risky participation for undergraduates is in analogue trauma research. I found that participants tolerated participation well and did not judge viewing a trauma film as worse than everyday stressors. Hence, analogue trauma research is not as risky (i.e., greater than minimal-risk definitions) as some IRBs and researchers suggest. Second, I investigated crowdsourced and undergraduate participants' views on consent guidelines, including whether their preferences differed based on prior trauma-exposure. Notably, trauma-exposed and non-trauma-exposed

participants had similar preferences for consent, indicating that unique considerations in ethical guidelines highlighting trauma-exposed people as a vulnerable population are unwarranted. Third, I explored whether consent risk-warnings used in trauma-related research contribute to negative outcomes for participants: they did not.

Together, my thesis contributes to our understanding of how to conduct trauma-related research with undergraduate and crowdsourced participants, in online settings. Notably, my thesis challenges some IRB and researcher concern that psychological trauma-related research is exceedingly risky. My research has implications for response expectancy theory and highlights the opportunity to develop theoretical models that account for informed consent and trauma-related research participation, from a psychological lens. Further, my work emphasises the need to continue reviewing our ethical research practices within psychology, and trauma-related research, to ensure that they are working for participants and go beyond being an institutional requirement. After all, we must balance the quest of building knowledge about—and developing treatments for—trauma-exposed people against adding more skeletons to the psychological research closet.

Supplementary Files

Table S9

Descriptive Statistics for Participants' Reactions to Research Participation Responses

Reactions to Research Participation Domain	*M(SD)*
Participation	3.35 (0.47)
Perceived Benefits	2.34 (0.76)
Emotional Reactions	2.72 (0.79)
Perceived Drawbacks	2.48 (0.82)
Global Evaluations	4.23 (0.56)

Table S10

Descriptive and Inferential Statistics for Comparisons Between Trauma-Exposed and Non-Trauma-Exposed Participants on Reactions to Research Participation Scores

Reactions to Research Participation Domain	Trauma-Exposed	Non-Trauma-Exposed				
	M(SD)	*M(SD)*	*t*	*df*	*p*	*Cohen's d*
Participation	3.41 (0.45)	3.31 (0.43)	36.18	41.10	.023	0.23
Perceived Benefits	2.36 (0.73)	2.35 (0.86)	0.64	44.26	.353	0.01
Emotional Reactions	2.83 (0.79)	2.41 (0.71)	27.75	42.94	.006	0.56
Perceived Drawbacks	2.36 (0.75)	2.60 (0.87)	56.37	40.51	.006	0.30
Global Evaluations	4.31 (0.49)	4.16 (0.60)	64.35	39.16	.010	0.27

Table S11

Descriptive and Inferential Statistics for Comparisons Between Trauma-Matched and Non-Trauma-Matched Participants on Reactions to Research Participation Scores

Reactions to Research Participation Domain	Trauma-Matched	Non-Trauma-Matched				
	M(SD)	*M(SD)*	*t*	*df*	*p*	*Cohen's d*
Participation	3.30 (0.58)	3.37 (0.43)	0.17	20.89	.751	0.14
Perceived Benefits	2.17 (0.76)	2.39 (0.76)	4.06	23.37	.115	0.29
Emotional Reactions	2.84 (0.86)	2.67 (0.79)	1.24	24.09	.231	0.21
Perceived Drawbacks	2.49 (1.04)	2.45 (0.77)	0.69	21.98	.361	0.04
Global Evaluations	4.26 (0.58)	4.22 (0.56)	0.03	23.28	.791	0.07

Figure S1

Expected Side-Effects for Participants in 'Imagined' Pilot Study

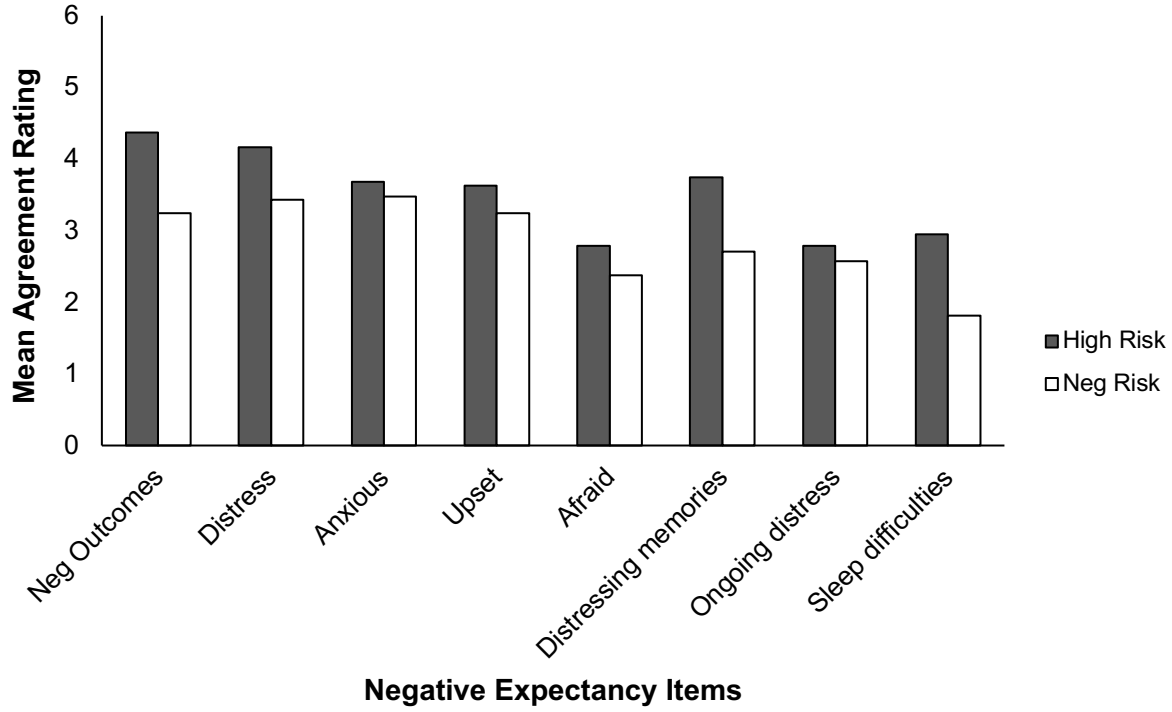
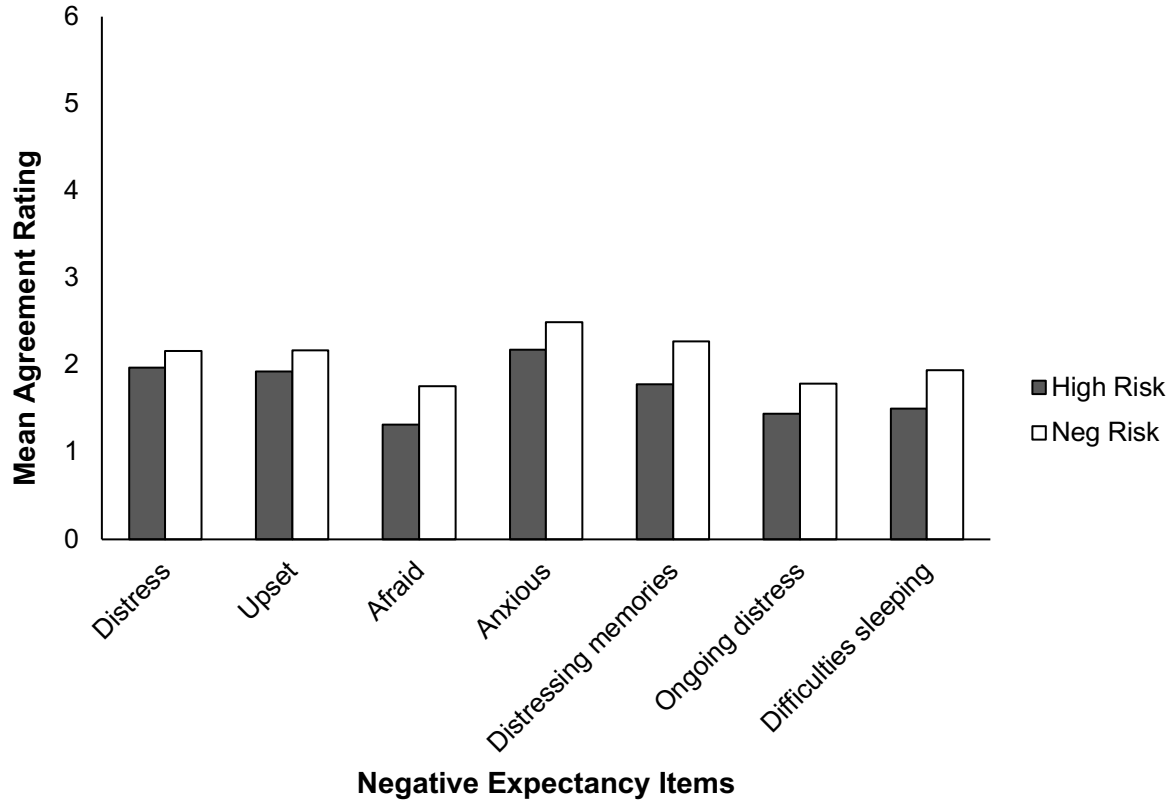


Figure S2

Expected Side-Effects for Participants in Study 3a



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Appendix A - Post-Test Reactions Questionnaire (Yeater et al., 2012)

Please indicate how much you agree or disagree with the following statements about the part of the study that you just completed, by selecting the appropriate number on each scale (where -3 = I strongly disagree, 0 = I feel neutral, and 3 = I strongly agree).

1. This study was boring.
2. This study was mentally exhausting.
3. This study was offensive to my values.
4. This study made me feel stupid.
5. This study made me feel embarrassed.
6. This study made me feel angry.
7. This study was intellectually challenging.
8. This study made me feel frightened.
9. This study made me feel like a bad person.
10. This study was emotionally exhausting.
11. This study sometimes made me feel sexually disgusted.
12. This study made me feel depressed.
13. This study made me feel sad.
14. This study made me feel unattractive.
15. This study made me feel aggressive.
16. This study was more upsetting than I expected.
17. This study made me feel like crying.
18. This study made me feel guilty.
19. This study made me feel emotionally unstable.
20. This study reminded me of horrible things in my past.
21. This study made me feel frustrated.
22. This study was too explicit about sexual topics.
23. This study gave me a headache.
24. This study made me feel discouraged.

25. If I had known before how I would react to this study, I would not have agreed to participate.
26. I wish I had never signed up for this study.
27. I felt that I was being exploited for scientific purposes.
28. I regret agreeing to participate in this study.
29. I found the experience of participating to be stressful.
30. The study made me think about things I didn't want to think about.
31. Thoughts about aspects of this study are bothering me.
32. I think I will experience distress in the future as a result of participating in this study.
33. This study was relaxing.
34. This study gave me insights into myself.
35. This study kept my attention.
36. This study was interesting.
37. This study helped me to feel better about myself.
38. This study made me feel happy.
39. This study made me feel relieved.
40. This study made me feel cheerful.
41. This study made me feel proud of what I have survived.
42. I would like to participate in more studies like this one.
43. I believe this study's results will be useful to others.
44. I think this research is for a good cause.
45. I like the idea I contributed to science.
46. I found participating in this study personally meaningful.
47. I liked knowing someone was paying attention to my thoughts and feelings.
48. Participating in this study was beneficial for me.
49. I experienced intense emotions during this study.

Appendix B - Normal Life Stressors Scale (Yeater et al., 2012)

We would like you to compare participating in this study to having some other life-experiences. We want to know which you would find more difficult, distressing, upsetting, or traumatic – which would be worse. For each event listed below, please indicate whether you think participating in this study would be worse than the event, or whether the event would be worse, by selecting the appropriate number from each scale (where -3 = This study was worse than the event described, 0 = This study was about equally bad and the event described, 3 = The event described would be much worse than this study).

1. Being arrested for a crime I did not commit.
2. Being fired from a summer job.
3. Being late to class.
4. Being lost in the wilderness.
5. Being racially abused on the street.
6. Being the victim of a robbery.
7. Being told I have bad breath on a first date.
8. Being woken without enough sleep.
9. Being wrongfully punished by a parent.
10. Breaking my new camera.
11. Disagreeing with my friend's life decisions.
12. Feeling hungover.
13. Feeling overworked.
14. Finding that a pet goldfish has died.
15. Getting a $100 speeding ticket.
16. Getting a bade grade in an important class.
17. Getting a paper cut on my thumb.
18. Having a cavity drilled and filled by a dentist.
19. Having a family member in hospital.
20. Having an argument with a family member.

21. Having blood drawn from my arm for a routine medical test.
22. Having my flatmate go on holidays without me.
23. Having my holiday cancelled at the last minute.
24. Having visa problems while travelling.
25. I am jealous of my friend's university achievements.
26. Learning that a family friend has died.
27. Losing $20.
28. Losing an important possession.
29. Missing out on seeing a film in the cinema.
30. My partner forgot my birthday.
31. Nearly having a car accident.
32. Oversleeping and being late.
33. Spilling coffee all over a new shirt.
34. Standing alone at a party where I don't know anyone.
35. Taking a difficult math test for an hour.
36. The death of a close family member.
37. Waiting in line for 20 minutes at a bank.
38. Watching a horror film that's scarier than I like.

Appendix C - Positive and Negative Affect Scale (PANAS; Watson et al., 1988)

This scale consists of a number of words that describe different feelings and emotions. Read each item and then select the appropriate answer. Indicate to what extent you currently feel this way (where 1 = very slightly or not at all, 2 = a little, 3 = moderately, 4 = quite a bit, 5 = extremely).

	Very slightly or not at all	**A little**	**Moderately**	**Quite a bit**	**Extremely**
1. Interested	1	2	3	4	5
2. Distressed	1	2	3	4	5
3. Excited	1	2	3	4	5
4. Upset	1	2	3	4	5
5. Strong	1	2	3	4	5
6. Guilty	1	2	3	4	5
7. Scared	1	2	3	4	5
8. Hostile	1	2	3	4	5
9. Enthusiastic	1	2	3	4	5
10. Proud	1	2	3	4	5
11. Irritable	1	2	3	4	5
12. Alert	1	2	3	4	5
13. Ashamed	1	2	3	4	5
14. Inspired	1	2	3	4	5
15. Nervous	1	2	3	4	5
16. Determined	1	2	3	4	5
17. Attentive	1	2	3	4	5
18. Jittery	1	2	3	4	5
19. Active	1	2	3	4	5
20. Afraid	1	2	3	4	5

Appendix D - Factors Affecting Decision to Participate

We would like you to read the following statements that relate to reasons why people might decide to participate in online psychology research studies. Please read each statement and indicate, using the scales below, to what extent you agree or disagree (where 0 = strongly disagree and 6 = strongly agree) with the statements. If you think that there is a reason that is not listed, please list the reason using the 'other' box and complete the same rating, that is, the extent to which you agree or disagree with the statement relating to participating in psychology research.

	0 = Strongly disagree	**1**	**2**	**3 = Neither agree nor disagree**	**4**	**5**	**6 = Strongly agree**
"I believe I'm contributing to science"	0	1	2	3	4	5	6
"I feel like these studies will help my own mental health"	0	1	2	3	4	5	6
"I feel like these studies benefit me financially"	0	1	2	3	4	5	6
"I feel like these studies are interesting"	0	1	2	3	4	5	6
"I feel like these studies are a good use of my time"	0	1	2	3	4	5	6
Other:	0	1	2	3	4	5	6

Appendix E - Informed Consent Stimuli

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Personality Traits and Responses to Emotional Film Scenes

Chief Investigator

[redacted]

Supervisor

[redacted]

Description and Purpose of the study

This project will investigate how people's personality traits interact with how they respond to, and cope with, emotional material. This project is supported by Flinders University, College of Education, Psychology, and Social Work.

Benefits of the study

The sharing of your experiences will help to further understand problematic negative events—which can result in clinical disorders such as posttraumatic stress disorder—and to develop appropriate psychological treatments. Participants may indirectly and directly benefit from such understanding and treatment in the future.

Participant involvement and potential risks

If you agree to participate in the research study, you will be asked to:

- Complete a series of online questionnaires relating to your mood, personality, and previous traumatic and/or stressful experiences.

- You will also view a short film clip containing emotionally sensitive material that depicts acted and real-life situations involving blood, injury, explicit physical or sexual violence or death. You will also be asked questions about your thoughts and feelings about the film.

Participation will take about 12 minutes and participation is entirely voluntary. Because this study will involve watching graphic scenes depicting blood, injury, explicit physical or sexual violence or death, participants may experience feelings of distress (for example, upset, afraid, or anxious). Participants may also experience distressing memories in the week after watching the film clip, as well as difficulties sleeping.

If required, you can also contact the following services for support:

- The National Suicide Prevention Service (1-800-273-8255) for 24-hour phone counselling
- Crisis Text Line (Text HOME to 741-741) for 24-hour text message hotline.

Withdrawal Rights

You may, without any penalty, decline to take part in this research study. If you decide to take part and later change your mind, you may, without any penalty, withdraw at any time without providing an explanation. To withdraw, please contact the Chief Investigator or you may just refuse to answer any questions / close the internet browser and leave the online survey /not participate in exercises at any time. Any data collected up to the point of your withdrawal will be securely destroyed.

Confidentiality and Privacy

Only researchers listed on this form have access to the individual information provided by you. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences, written up for publication or used for other research purposes as

described in this information form. However, the privacy and confidentiality of individuals will be protected at all times. You will not be named, and your individual information will not be identifiable in any research products without your explicit consent.

No data, including identifiable, non-identifiable and de-identified datasets, will be shared or used in future research projects without your explicit consent.

Data Storage

The information collected may be stored securely on a password protected computer and/or Flinders University server throughout the study. Any identifiable data will be de-identified for data storage purposes unless indicated otherwise. All data will be securely transferred to and stored at Flinders University for five years after publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

Recognition of Contribution

If you would like to participate, in recognition of your contribution and participation time, you will be provided with $1.20 (USD).

How will I receive feedback?

On project completion, a short summary of the outcomes will be provided to all participants via email or published on Flinders University's website.

Ethics Committee Approval (i.e., Institutional Review Board)

The project has been approved by Flinders University's Human Research Ethics Committee (5312).

Queries and Concerns

Queries or concerns regarding the research can be directed to the research team. If you have any complaints or reservations about the ethical conduct of this study, you may contact the

Flinders University's Research Ethics & Compliance Office team via telephone 08 8201 2543 or email human.researchethics@flinders.edu.au.

Thank you for taking the time to read this information sheet. Please proceed to the consent form on the following page.

CONSENT FORM

Consent Statement

- I have read and understood the information about the research, and I understand I am being asked to provide informed consent to participate in this research study. I understand that I can contact the research team if I have further questions about this research study.
- I am not aware of any condition that would prevent my participation, and I agree to participate in this project.
- I understand that I am free to withdraw at any time during the study.
- I understand that I can contact Flinders University's Research Ethics & Compliance Office if I have any complaints or reservations about the ethical conduct of this study.
- I understand that my involvement is confidential, and that the information collected may be published. I understand that I will not be identified in any research products.

I further consent to:

- completing questionnaires
- viewing a short film clip containing emotionally sensitive material

Appendix F - State-Trait Anxiety Inventory: Short-Form (Marteau & Bekker, 1992)

A number of statements which people have used to described themselves are provided below. Read each statement and then select the most appropriate rating to the right of the statement to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Appendix G - Anticipated Emotion Questionnaire

Please rate the extent to which you agree with the following statements (where 0 = I strongly disagree, 3 = I neither agree nor disagree, and 6 = I strongly agree):

1. I expect to feel distressed.
2. I expect to feel happy.
3. I expect to feel upset.
4. I expect to feel energetic.
5. I expect to feel afraid.
6. I expect to feel anxious.
7. I expect to feel excited.
8. I expect to experience distressing memories.
9. I expect to experience ongoing psychological distress.
10. I expect to experience difficulties sleeping.

Appendix H - Balanced Inventory of Desirable Responding: Short Form (Hart et al., 2015)

Using the scale below, please select a number that indicates how much you agree with each statement (where 1 = Not true, 4 = Somewhat true, 7 = Very true):

1. I have not always been honest with myself.
2. I always know why I like things.
3. It's hard for me to shut off a disturbing thought.
4. I never regret my decisions.
5. I sometimes lose out on things because I can't make up my mind soon enough.
6. I am a completely rational person.
7. I am very confident of my judgments.
8. I have sometimes doubted my ability as a lover.
9. I sometimes tell lies if I have to.
10. I never cover up my mistakes.
11. There have been occasions when I have taken advantage of someone.
12. I sometimes try to get even rather than forgive and forget.
13. I have said something bad about a friend behind his or her back.
14. When I hear people talking privately, I avoid listening.
15. I never take things that don't belong to me.
16. I don't gossip about other people's business.

Appendix I - Reading Task Stimuli

Time

Scientists can't tell you what time it is, only how to measure it. There are two important questions you can ask about time. You can ask what it is, and you can ask how to measure it. The first question is the domain of philosophers, mystics, and others who like dealing with insoluble problems. Physicists only deal with how to measure time. St. Augustine in his Confessions, said "What is time? If no one asks me, I know what it is. If I wish to explain what it is to him who asks me, I do not know." This is probably as good a definition as you're likely to get.

In order to measure time, you must have a regularly occurring phenomenon in nature. The standard is to find something that happens regularly, and then define the unit of time in terms of the reappearance and recurrence of the phenomenon. For example, one unit of time is the "day" – the time between two successive sunrises. All systems for measuring time depend, ultimately, on the recurring phenomenon that is chosen to define the basic standard.

Throughout most of human history the passage of time has been measured in terms of the day (which is related to the time it takes the earth to turn once on its axis) and the year (the time it takes the earth to go once in its orbit around the sun).

The first exercise in measurement of time was the production of the calendar. When human beings began to develop agriculture, it became necessary for them to mark important events like the planting of time for particular crops. In other words, they had to have a calendar. The calendar is really a clock that "ticks" once a year and therefore keeps track of where the earth is in its orbit around the sun. It is this position that determines the seasons.

The basic problem of constructing a calendar is that the number of days in a year is not an even number. The following calendars represent successive approximations to the true length of the year:

Egyptian Calendar

This calendar consisted of twelve months of thirty days each, followed by a five-day party. The problem with the Egyptian calendar arose from the fact that there are approximately 365 ¼ days in a year, not 365. This meant that the calendar would "slip" a quarter day every year. These slippages built up, and, if you had followed things blindly, would eventually have led to a situation where you had the Egyptian equivalent of snow in "August".

Julian Calendar

The calendar introduced by Julius Caesar tried to bring some order into time keeping in the Roman Empire. It solved the problem of the extra quarter day by introducing the leap year. Every four years the year is one day longer, and this makes up for most of the slippage that appeared in the Egyptian calendar. It didn't catch all of it, though, because the year is 11 minutes 14 seconds shorter than 365 ¼ days. These errors started to accumulate (they amount to 7 days every 1000 years) until they begun to mess up the observance of Easter. This led to the…

Gregorian Calendar

The Gregorian calendar was introduced by Pope Gregory in 1582 to deal with the accumulated slippage in the Julian calendar. It works by dropping leap years when they fall on centennials except when the centennial is divisible by four. Thus, 200 will retain its leap year while 1700, 1800, and 1900 did not. The Gregorian calendar is the one we use today and

the one with which you are familiar.

However, Russia didn't adopt the Gregorian calendar until after the revolution. Thus, for several centuries, there were two calendars operating in Europe – the Gregorian in most of the west, the Julian in the east. This explains why you often see dates in Russian history given twice – one in modern (Gregorian) terms, the other in "old style" (Julian) terms.

Stars

Stars, like everything else, are born, live out their lives, and die. It was only fairly recently in the history of the human race – the nineteenth century, to be exact – that people realised that stars couldn't last forever. Stars are continually pouring energy into space, and that energy has to come from somewhere. Today, we know that the sun, like most stars, burns hydrogen to produce that energy. But even for a huge body like the sun, that supply is not endless. The sun, like a campfire, will someday stop burning and die.

There were some interesting attempts to explain the energy output of the sun. In the nineteenth century scientists showed that if it were made of pure anthracite coal (the best fuel known at the time) it could only last for 10,000 years at its present rate of energy output.

The energy source of the stars is nuclear fusion. Deep inside the sun, nuclei of hydrogen come together in a series of reactions whose end product is helium and some excess energy. The sun consumes hydrogen at the rate of 700 million tons per second, and it has done so since shortly after it formed. Most other stars generate energy in the same way for most of their lifetimes, only going on to other things when the hydrogen is exhausted.

A star's life is a battle between the nuclear fires and gravity. The force of gravity is always pulling the star in on itself. For a while, the star can maintain a precarious equilibrium by using the energy from nuclear reactions to balance in inward pull. The life of every star is a battle between these two competing forces. Eventually, the fuel must run out and gravity will win. It is the victory of gravity that we refer to as the death of the star.

Not all stars are like the sun. If you think of the sun as being roughly the size of a basketball, the range of other stars would go from those the size of a grain of sand to those the size of a large building. Stars come in all brightness's, colours, and many very exotic forms. Amidst all this variety, the sun is a very ordinary star. It is average in its lifetime, its chemical composition and its luminosity. There is absolutely nothing to distinguish it from it brethren in the Milky Way.

The brightness of a star is measured in terms of its "magnitude". Before the invention of the telescope, stars were grouped by what we would today call their apparent magnitude – that is, their brightness as seen from earth. The brightest stars were said to be first magnitude, the next brightest second magnitude, and the dimmest that can be seen with the naked eye sixth magnitude. This scheme was retained by astronomers even after the invention of the telescope. Each drop in magnitude corresponds to a drop of 2.5 in the brightness of the source as seen from earth. Thus, a sixth magnitude star is approximately 100 times dimmer than the first magnitude. It is not at all unusual today for astronomers using state-of-the-art telescopes to detect twenty-fourth magnitude objects in the sky.

The apparent brightness of a star depends on how far way it is and on how much energy it is giving odd (its "luminosity"). To eliminate the ambiguity associated with the distance of the

star, astronomers have defined the “absolute magnitude” of a star as the brightness it would have if it were seen from a distance of thirty-three light years. The absolute magnitude does not depend on the distance to a star, but measures something intrinsic to the star itself.

Appendix J - Phenomenological Experience of Intrusions

Please rate the following statements and questions as to how well they describe your memory (or memories) of the film coming to mind when reading the science articles (where 0 = Not at all and 7 = Extremely).

1. The memory came to mind spontaneously at the time it occurred.
2. The memory came to mind effortlessly.
3. How distressing was the memory when it came to mind?
4. How vivid was the memory when it came to mind?
5. How intense were the emotions you felt when the memory came to mind?
6. How much did the event feel as though it was happening “right now” when the memory occurred?
7. How unpleasant was the memory when it came to mind?
8. How unwanted was the memory when it came to mind?
9. While having the memories of the film, were the emotions you felt negative or positive? (0 = Extremely negative and 7 = Extremely positive)
10. To what extent did you try and suppress/push the thoughts about the film out of your mind?

Appendix K - Reactions to Research Participation Questionnaire (RRPQ; Newman et al., 2001)

The following questions deal with your reactions to participating in this study. Please indicate the number that best describes your response (where 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree):

1. I gained something positive from participating.
2. Knowing what I know now, I would participate in this study if given the opportunity.
3. The research raised emotional issues for me that I had not expected.
4. I gained insight about my experiences through research participation.
5. The research made me think about things I didn't want to think about.
6. I found the questions too person.
7. I found participating in this study personally meaningful.
8. I believe this study's results will be useful to others.
9. I trust that my replies will be kept private.
10. I experienced intense emotions during the research session and/or parts of the study.
11. I think this research is for a good cause.
12. I was treated with respect and dignity.
13. I found participating beneficial to me.
14. I was glad to be asked to participate.
15. I like the idea that I contributed to science.
16. I was emotional during the research session.
17. I felt I could stop at any time.
18. I found participating boring.
19. The study procedures took too long.
20. Participating in this study was inconvenient for me.
21. Participation was a choice I freely made.
22. Had I known in advance what participating would be like I still would have agreed to participate.
23. I understood the consent form.