



# Insult, then Injury: Interpersonal and Institutional Betrayal Linked to Health and Dissociation

Carly P. Smith<sup>a</sup> and Jennifer J. Freyd<sup>b</sup>

<sup>a</sup>Department of Humanities, College of Medicine, Penn State University, Hershey, Pennsylvania, USA; <sup>b</sup>University of Oregon, Eugene, Oregon, USA

#### ABSTRACT

Psychological trauma, particularly trauma involving betrayal, has been linked to health problems. Betrayal trauma is also characterized by dissociation and difficulty remembering as victims face conflicting demands presented by a harmful but important relationship. Institutional betrayal is related to, but distinct from, interpersonal betrayal and in need of research on its unique effects. The current study has two related goals. First, the association between institutional betrayal and health problems is examined. Second, the previously documented association between institutional betrayal and dissociative symptoms is re-examined, while controlling for betrayal trauma. This study utilizes a sample of 302 college students (70% female, 63% Caucasian) who reported their trauma history (Brief Betrayal Trauma Survey), institutional betrayal history (Institutional Betrayal Questionnaire), distress related to health problems (Patient Health Questionnaire), and dissociative symptoms (Wessex Dissociation Scale). We found that institutional betrayal is uniquely associated with both health problems and dissociative symptoms even when controlling for betrayal trauma exposure. Findings add to the understanding of how institutional betrayal is uniquely associated to trauma-related physical and mental health outcomes. Small effect sizes, likely due to low base rates of health problems and dissociative symptoms in college students, and problems generalizing these results to clinical samples are discussed.

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#### **KEYWORDS**

Dissociation; health; institutional betrayal; trauma; trauma-informed care

The Diagnostic and Statistical Manual of Mental Disorders defines a traumatic event in the context of diagnostic criteria for posttraumatic stress disorder: the exposure to actual or threatened death, serious injury, or sexual violence (American Psychiatric Association, 2013). Within those categories, however, is a range of experiences (e.g., severity of coercion or repeat victimization in sexual violence; French, Bi, Latimore, Klemp, & Butler, 2014) that may lead to more complicated posttraumatic distress. One such complication is distress that affects both mental and physical health, a common occurrence in interpersonal violence (Lacey, McPherson, Samuel, Sears, & Head, 2013).

CONTACT Carly P. Smith a carly.smith@.psu.edu Penn State College of Medicine, Department of Humanities, 500 University Drive, Hershey, PA, 17033.

The study of traumatic stress has revealed the toll of psychological trauma on physical health (e.g., Engelhard, van den Hout, Weerts, Hox, & van Doormen, 2009; McFarlane, 2010). A conclusion from this body of research is that chronic or complex stressors (i.e., arising from multiple sources) take a greater toll on health. One such stressor is betrayal trauma, which occurs when the perpetrator of interpersonal violence or maltreatment (e.g., child neglect) is trusted or depended-upon (e.g., a parent or caregiver; Freyd, 1996). Betrayal trauma is likely to be both a chronic and complex stressor; because it is perpetrated by someone close to the victim this type of maltreatment is often on-going and multifaceted. Betrayal trauma has been strongly linked to health outcomes (Freyd, Klest, & Allard, 2005; Goldsmith, Freyd, & DePrince, 2012; Klest & Freyd, 2007; Klest, Freyd, Hampson, & Dubanoski, 2013; Mackelprang et al., 2014).

Betrayal trauma has also been closely linked to memory for abuse, with closeness of the victim-perpetrator relationship positively associated with increased forgetting of abuse (Freyd, Deprince, & Zurbriggen, 2001). This lack of awareness serves an adaptive function: it may allow victims of betrayal, particularly those who continue to depend upon their perpetrators for survival, safety, or other resources, to maintain these relationships (Freyd, 1996). Lack of awareness of abuse may encompass awareness of one's own responses to abuse, which takes the form of dissociation—a cognitive distancing from one's physical and emotional experiences (van der Kolk, Roth, Pelcovitz, Sunday, & Spinazzola, 2005; Zurbriggen & Freyd, 2004). Victims of complex trauma are likely to move their awareness from psychological "knowing" about the harm they have experienced to the physical realm (e.g., van der Kolk, 1994). Repeated exposure to trauma has also been associated with difficulty identifying feelings as well as misattributing psychological distress as physical, a phenomenon known as somatization (Polusny, Dickinson, Murdoch, & Thuras, 2008).

Interpersonal relationships are not the only sources of betrayal; more recent work has indicated that individuals are at risk of being betrayed by trusted or important institutions when those institutions fail to protect them or respond negatively to traumatic events, such as sexual violence (Smith & Freyd, 2013, 2014). Institutional betrayal is an unwelcome addition to a traumatic experience; it leaves its own mark on the mental health of victims (Lueger-Schuster et al., 2014; Monteith, Bahraini, Matarazzo, Soberay, & Smith, 2016; Wright, Smith, & Freyd, 2016) as well as exacerbating posttraumatic distress (Smith & Freyd, 2013). Previous studies of institutional betrayal have measured the degree to which it exacerbates a traumatic experience (Smith & Freyd, 2013) as well as the degree to which it uniquely predicts stress-related outcomes (Wright, Smith, & Freyd, 2016). However, these prior studies have measured interpersonal violence using scales that do not differentiate between betrayal and non-betrayal traumas [e.g., the Sexual Experiences Scale (Koss et al., 2007); the Life Events Checklist (Gray, Litz, Hsu, & Lombardo, 2004)]. Thus, although the effect of institutional betrayal on mental health and interpersonal functioning has been demonstrated, it is not

known whether these effects are independent from interpersonal betrayal. This leaves an important gap in understanding how institutional betrayal works as a traumatic stressor. For example, research has suggested that victims who know their perpetrator may be more reluctant to report sexual assault out of fear of not being believed (Zinzow & Thompson, 2011). Other research has demonstrated these expectations to be borne of many victims' experiences: social reactions to victims of child sexual abuse perpetrated by relatives tended to be more negative than reactions to victims of stranger-perpetrated abuse (Ullman, 2007). Therefore, it may be that the effects of institutional betrayal may be closely related to interpersonal betrayal. In order to truly understand the unique effect of each type of betrayal, they must be assessed and tested concurrently.

# **Current study**

The current study examines two hypotheses, both of which aim to clarify the role of institutional betrayal in traumatic experiences and outcomes. The first hypothesis posits that institutional betrayal will predict physical health symptoms, as measured on the Patient Health Questionnaire (Kroenke, Spitzer, & Williams, 2002), while controlling for betrayal trauma. The second hypothesis posits that institutional betrayal will predict cognitive symptoms of dissociation, as measured on the Wessex Dissociation Scale (Kennedy et al., 2004), while controlling for betrayal trauma. Although we expect that both types of betrayal will be associated with each of these outcomes, testing them together allows us to examine whether institutional betrayal is a unique aspect of traumatic experiences.

#### Method

# **Participants**

Our sample consisted of 302 undergraduates who were eligible (i.e., over 18 years old) participants in a human subject pool as part of their enrollment in an introductory psychology course at a public research university in the Pacific Northwest. They received course credit for completing an online survey that consisted of several measures compiled by researchers within the psychology department that were divided into blocks estimated to take approximately 30 minutes to complete (commonly referred to as the 'general survey'). Therefore, participants did not select this study based on knowledge of or interest in the topic. Participants provided demographic information as part of their participation in the human subjects pool. The sample reflected the demographics of the human subject pool: 70% female; 63% Caucasian, 13.6% Asian, 9% Latino/a, 4% African American; mean age was 19.15 years (SD = 3.67).

#### Measures

# Betrayal trauma

Interpersonal betrayal trauma was assessed using the Brief Betrayal Trauma Survey (BBTS; Goldberg & Freyd, 2006). The BBTS is a brief self-report checklist that presents two low betrayal items (experiencing natural disasters and accidents), three medium betrayal items (witnessing violence, being physically or sexually abused by someone to whom they are not close), and five high betrayal items (witnessing someone close experience violence or commit domestic abuse; being physically, sexually, or emotionally abused by someone close). For analyses in this study, the BBTS was scored categorically where participants were classified by the highest betrayal trauma they had experienced-none, low, medium, or high (i.e., someone who endorsed both low and medium betrayal traumas would be classified in the medium betrayal category). Prior research on the test-retest reliability of the BBTS indicates that responses are relatively consistent over time, with 72-78% agreement between two time points (Goldberg & Freyd, 2006).

# Institutional betrayal

Institutional betrayal associated with the events reported on the BBTS was assessed using an expanded form of the Institutional Betrayal Questionnaire (IBQ; Smith & Freyd, 2013). The IBQ asks respondents to consider the experiences they just described (in this case, on the BBTS) and indicate whether an institution was involved in any way. Examples of institutions are given (e.g., universities, military, organized religions) as well as examples of parts of institutions (e.g., a fraternity or sorority, a military unit, or a particular church). The original seven institutional betrayal items of the IBQ are included as are five new items: Denying your experience in some way; Punishing you in some way for reporting the experience (e.g., loss of privileges or status); Suggesting your experience might affect the reputation of the institution; Creating an environment where you no longer felt like a valued member of the institution; and Creating an environment where continued membership was difficult for you. Respondents also report how strongly they identified with the institution prior to this experience (1 = Not at all, 4 =Very much), whether they are still members of the institution (Yes/No), and briefly describe the institution involved by typing directly into the online form.

For analyses in this study, the IBQ was scored dichotomously as either experiencing institutional betrayal or not (where participants were classified as having experienced institutional betrayal if they checked any of the 12 items describing institutional actions). Using a categorical approach to describe betrayal trauma is quite common (Caretaker/Non-Caretaker, Freyd et al., 2001; High, Medium, Low, Goldberg & Freyd, 2006; Kaehler & Freyd, 2009). For institutional betrayal, there is no wording of the items that differentiates between low or medium institutional betrayal and high (as with the BBTS where interpersonal abuse can be differentiated by closeness to perpetrator); there is only the presence or absence of institutional actions or inactions, thus the dichotomous scoring used here.

# Health problems

Distress related to health was assessed with the Somatization scale of the Patient Health Questionnaire (PHQ-15; Kroenke et al., 2002). The PHQ-15 is a 15-item scale that measures distress associated with physical symptoms, such as stomach pain, headaches, shortness of breath, and trouble sleeping, that are common symptoms of Somatization Disorder but also map well onto physiological response to chronic stress. Respondents indicate how bothered they have been by each symptom (0 = Not at all, 4 = Extremely) during the past 4 weeks. The PHQ-15 has been demonstrated to predict functional health, healthcare utilization, and self-reported sick days (Kroenke et al., 2002). In the current sample, the PHQ-15 demonstrate good internal consistency ( $\alpha = .87$ ) and met assumptions of normality (Skew = 0.87, SE = 0.14; George & Mallery, 2010).

### Dissociation

Dissociative symptoms were measured with the Wessex Dissociation Scale (WDS; Kennedy et al., 2004). The WDS is a 40-item measure that was developed to assess a wider range of dissociative symptoms than other dissociation scales, including cognitive dissociative styles that may be more prevalent in non-clinical populations. Respondents indicate how bothered they have been by each symptom (0 = Never, 5 = All the time). The WDS has demonstrated convergent validity with other dissociation scales and measures of psychopathology (Kennedy et al., 2004). In the current sample, the Wessex demonstrate good internal consistency  $(\alpha = .96)$  and met assumptions of normality (Skew = 1.50, SE = 0.14; George & Mallery, 2010).

# Statistical analyses

All data were analyzed using version 23 of the Statistical Package for the Social Sciences (SPSS). Analysis of variance (ANOVA) was used to test the unique main effects of betrayal trauma and institutional betrayal on the two outcomes of interest, health problems, and dissociation. The models used a two-way ANOVA (i.e., No, Low, Medium, and High Betrayal by No Institutional Betrayal, Any Institutional Betrayal). Because this is an initial exploration of the unique effects of interpersonal and institutional betrayal, we are using categorical scores for our independent variables. This allows us to test the differences between participants who have had qualitatively different experiences (e.g., those who have experienced high interpersonal betrayal with or without institutional betrayal). Effect sizes for each main effect are reported as partial Eta-squared ( $\eta^2$ ), which represents the proportion of variance in the outcome explained by the variable, while controlling for the effect of the other variable in the model (Richardson, 2011).

#### **Results**

# Descriptives

Many participants (n = 125; 41.40%) reported experiencing high betrayal trauma. Over half of the participants reported at least one traumatic event on the BBTS (n = 176; 58.28%), and of those participants half reported institutional betrayal related to these events (n = 88; 50.00%), see Figure 1a for number of participants experiencing each level of betrayal trauma and institutional betrayal. For participants who experienced institutional betrayal, the average number of IBQ items endorsed was 2.52 (SD = 1.99). The most common form of institutional betrayal reported was "Not taking proactive steps to prevent this type of experience" (n = 52; 59.09%) followed by "Creating an environment in which this type of experience seems common or normal" (n = 29; 32.95%). Of participants who had experienced institutional betrayal, 34.10% reported

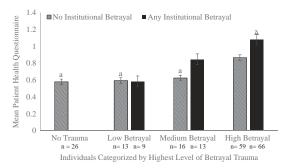
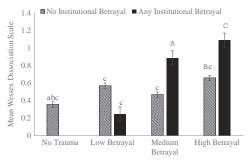


Figure 1. (a) Symptoms reported on the patient health questionnaire somatization subscale. Note. Numbers below bars in Figure 1(a) reflect number of participants in each group. There is no institutional betrayal bar for the No Trauma group because institutional betrayal is experienced in relation to a traumatic event. Error bars reflect  $\pm$  one standard error of mean by institutional betrayal group. Significant post-hoc comparisons (Tukey's HSD test) are indicated by letters above each bar; uppercase bolded letters are significantly larger than lowercase letters.



Individuals Categorized by Highest Level of Betrayal Trauma

Figure 1. (b) Symptoms reported on the Patient Health Questionnaire Somatization Subscale and Wessex Dissociation Scale.

that they were still a member of that institution. The most common institution reported was a university or school (n = 44; 50.00%). Overall, the sample reported little distress due to health problems (M = 0.766, SD = 0.54, range = 0 to 2.40; see Figure 1a) and low levels of dissociation (M = 0.61, SD = 0.62, range = 0 to 2.85; see Figure 1b).

#### Expanded IBQ

The newly added items were endorsed at rates comparable to existing items (between 11.36% and 29.55% endorsed these items). The new items were significantly associated with both physical health problems and dissociation (see Table 1). When scoring the IBQ for use in the ANOVA (i.e., creating a dichotomous None/Any variable), 12 additional participants were added by using the new items versus using only the original seven items. The interpretation of the results of the ANOVA described below did not meaningfully differ when the new IBQ items were included in the scoring of the institutional betrayal variable but the effect sizes did increase. Together these results indicate the new items are valid additions to the IBQ.

# **ANOVA**

Health problems assessed on the PHQ-15 significantly differed by betrayal trauma history, F(3, 297) = 7.29, Partial  $\eta^2 = .07$ , p < .001, and institutional betrayal, F(1, 297) = 6.37, Partial  $\eta^2 = .02$ , p = .01. Dissociation symptoms assessed on the WDS also significantly differed by betrayal trauma history, F(3, (297) = 8.02, Partial  $\eta^2 = .08$ , p < .001, and institutional betrayal, F(1, 297) = 16.95,

Table 1. New IBQ items and mean differences in physical health and dissociation.

IBQ		Health ( M (			Dissociati M (				
Item	N (% IB)	Absent	Present	t	р	Absent	Present	t	р
8	20 (22.72)	0.56 (0.56)	1.26 (0.77)	5.19	<.001	0.72 (0.52)	1.29 (0.57)	4.70	<.001
9	10 (11.36)	0.58 (0.55)	1.58 (1.04)	5.42	<.001	0.75 (0.53)	1.11 (0.63)	2.09	.04
10	14 (15.90)	0.59 (0.58)	1.01 (0.91)	2.54	.01	0.76 (0.54)	0.81 (0.55)	0.04	.70
11	26 (29.55)	0.58 (0.58)	0.96 (0.75)	3.17	.002	0.74 (0.52)	0.99 (0.67)	2.32	.02
12	24 (27.27)	0.58 (0.56)	0.98 (0.89)	3.20	.002	0.74 (0.52)	0.95 (0.65)	1.79	.08

Note: IBQ items are: Denying your experience in some way? Punishing you in some way for reporting the experience (e.g., loss of privileges or status)? Suggesting your experience might affect the reputation of the institution? Creating an environment where you no longer felt like a valued member of the institution? Creating an environment where continued membership was difficult for you?

Table 2. Analysis of variance (ANOVA) between betrayal trauma, institutional betrayal measured via original and revised IBQ, and two outcomes: Health and dissociation.

		Revised IBQ—12 item					Original IBQ—7 item					
					Partial						Partial	
	SS	df	MS	F	η²	р	SS	df	MS	F	η²	р
Health (PHQ-15)												
Betrayal Trauma <sup>1</sup>	5.47	3	1.82	7.29	.07	<.001	6.66	3	2.22	8.78	.08	<.001
Institutional	1.59	1	1.59	6.37	.02	.01	0.68	1	0.68	2.67	.01	.103
Betr. <sup>2</sup>												
Error	74.27	297	0.25				75.19	297	0.25			
Dissociation (WDS)												
Betrayal Trauma <sup>1</sup>	6.96	3	2.32	8.02	.08	<.001	8.08	3	2.69	9.24	.09	<.001
Institutional	4.90	1	4.90	16.95	.05	<.001	4.24	1	4.24	14.57	.05	<.001
Betr. <sup>2</sup>												
Error	85.84	297	0.29				86.50	297	0.29			

<sup>&</sup>lt;sup>1</sup>Betrayal Trauma refers to the most severe form (high, medium, low, and no trauma) that participants

Partial  $\eta^2 = .05$ , p < .001. See Table 2 for these ANOVA coefficients and for those using only items from the original IBQ scale.

# **Discussion**

Institutional betrayal is increasingly recognized as an added risk for trauma victims, conferring many of the same risks as interpersonal betrayal (Monteith et al., 2016; Smith & Freyd, 2013; Wright et al., 2016. This study continued the investigations into the parallels between interpersonal betrayal trauma and institutional betrayal, while also attempting to discern the unique impact of the two types of betrayal. We found that institutional betrayal does indeed relate to both health

<sup>&</sup>lt;sup>2</sup>Institutional Betrayal refers to a dichotomous classification of participants' experience of institutional betrayal (none, any) related to the trauma they reported on the BBTS.

and dissociation, in keeping with betrayal trauma theory, but does so of its own accord—unique from the effects of interpersonal betrayal.

# Institutional betrayal and health

Although institutional betrayal may share many of the same outcomes as interpersonal betrayal, there are unique aspects that may explain the link to health problems. Traumatic events that are inherently high in institutional betrayal due to deep institutional affiliations and documented institutional efforts to cover up rather than respond to wrongdoing (e.g., military sexual trauma, clergy sexual abuse) have been strongly linked to negative health outcomes (Baltrushes & Karnik, 2013; Disch & Avery, 2001; Sadler, Booth, & Doebbeling, 2005). Research on the role of environment in stress response indicates that exposure to the environment of a previous stressor is enough to elicit a strong physiological stress response in animals (Grissom, Iyer, Vining, & Bhatnagar, 2007). Repeated, prolonged, or uncontrollable stress responses are a key part of most models linking traumatic experiences to adverse physical health outcomes (Segerstrom & Miller, 2004).

Traumatic experiences that include institutional betrayal may introduce an environment where reminders of trauma are nearly impossible to avoid or manage: imagine a college student living on campus whose sexual assault occurred following a university-sanctioned event and whose report to student services went unanswered (all sources of institutional betrayal). Where would she be able to go to escape cues that triggered memories of this experience? How many times per day would she be reminded of how her trust in her university had been betrayed? A critical source of distress for individuals with posttraumatic stress disorder is constant vigilance for and avoidance of reminders of traumatic events (Pineles et al., 2011). Recent research in a college sample on the role of experiential avoidance, or internal attempts to avoid stress responses, indicates that physical health problems increase as students attempt to suppress these reactions to reminders of traumatic events (Sowder, 2016). Finally, institutional betrayal may function as a barrier to accessing services for either mental or physical health as victims of trauma may be unwilling to trust an institution with their care (Chartier, Walker, & Naimark, 2007).

# Institutional betrayal and dissociation

Institutional betrayal may present a special challenge for individuals that have also experienced betrayal trauma. Often, interpersonal betrayal occurs within primary relationships (e.g., perpetrated by parents or other caregivers) that are not necessarily chosen by the victims (Freyd, 1996). However, later institutional affiliation often are chosen by individuals, sometimes in an attempt to escape sources of early life betrayal—for example, there is twice the rate of childhood sexual abuse in female military personnel than their civilian counterparts and many of these women cite escaping home environments as reasons they initially joined the military (Rosen & Martin, 1996; Sadler, Booth, Mengeling, & Doebbeling, 2004). Leaving an institution in which one found identity and refuge from one type of abuse may represent an unbearable loss, even if it means enduring further maltreatment, a pattern all too common in victims of ongoing abuse (Murray, 2008). To resolve the dissonance created by this choice, many individuals may appear to adopt a dissociative coping style, remaining consciously "unaware" of institutional betrayal to maintain their membership (Freyd & Birrell, 2013). Unfortunately, this leaves them exposed to ongoing institutional betrayal and the related toll it may take on their health.

# Health and dissociation: Linked by betrayal?

One of the strengths of this study is the direct measurement of both interpersonal betrayal via the BBTS and institutional betrayal via the newly expanded IBQ. Measuring these two constructs together allowed to examine their unique contribution to two important outcomes of betrayal: physical health problems (assessed here by the physical health complaints measured by the Patient Health Questionnaire) and dissociation (assessed via the Wessex Dissociation Scale). These outcomes are not just theoretically and empirically related to betrayal; it may be that they co-occur for individuals who have experienced institutional betrayal (see Table 1 for mean differences by institutional betrayal) as they both arise from the need to keep betrayal out of conscious awareness as an adaptation to complex stress (van der Kolk et al., 2005).

One implication of this work is how it may inform clinicians. Individuals who present for treatment with difficult to diagnose physical health complaints or distress associated with their physical health should be asked about trauma (e.g., Walker et al., 1995) and institutional betrayal, particularly in setting where incidence rates on institutional betrayal may be especially high. This includes environments where increased rates of trauma have been identified but no clear solutions have yet been found, such as the problem of sexual assault on college campuses. Even in the current sample of college students, where overall distress due to physical health problems was low and dissociative symptoms were relatively rare, both were significantly higher for those students who had experienced betrayal trauma and higher still for those who had experienced institutional betrayal.

# Limitations and future directions

This study was comprised of college students, like many other social science studies, and introduces the possibility that our results are not generalizable beyond this population (Henrich, Heine, & Norenzayan, 2010). Certainly, the sample was different from one comprised of patients in a hospital or individuals recruited through mental health services; the sample average for both the PHQ and the WDS were quite low. The PHQ is typically used in conjunction with healthcare visits and previous research on the WDS with non-clinical samples have also documented low rates of dissociative experiences (M = 0.88, SD = 0.38; Kennedy et al., 2004). This likely impacts the effect sizes observed and our sample itself was small enough that, combined with small effect sizes, we were unable to test more complex models. Both aspects limited how far we can generalize our data beyond college students. However, much of the criticisms of conducting psychological research with college students is that they are relatively advantaged and privileged and, thus, their experiences are not necessarily relevant to understanding realworld phenomena (Henrich et al., 2010). In the current sample, a trauma history was more common than not and institutional betrayal accompanied fully half of those experiences. To reiterate, this was **not** a self-selected sample that chose a study about trauma because they had something to describe, which is a threat to external validity present in many studies (Freyd, 2012). This rate of trauma is quite comparable the national average (Acierno & Resnick, 1997). Further, should college students represent a population that is more protected from the effects of these types of experiences, then our observed results may be interpreted as underestimating the impact of both betrayal trauma and institutional betrayal. One effect of this constrained sample is evident from the majority of responses to the IBQ that were based on the actions of a university or school, representing the centrality of this type of institution in the lives of college students. It may be that other institutions may be more relevant to other populations (e.g., patients in healthcare systems, members of religious organizations) and that institutional betrayal in these settings may affect victims of trauma differently. In any event, further research is needed to understand how these experiences may affect a wider range of individuals.

# **Conclusion**

In order to fully understand the impact of traumatic experiences on physical and mental health, both interpersonal and institutional betrayal should be taken into account. The model of betrayal trauma theory (Freyd, 1996) affords a framework for understanding why institutional betrayal may lead to physical health problems due to both chronic stress as well as dissociated psychological distress. The current study bears out these predictions empirically, demonstrating that institutional betrayal represents a unique source of added harm that is an altogether too common experience among trauma victims who may already bear the burden of betrayal. In our results, the institutions responsible were mostly schools or universities that failed to prevent or respond supportively to their students who experienced interpersonal violence. Yet these results are reported in a larger context: a society in which recognition is growing for the role of institutions in traumatic experiences (e.g., religious institutions harboring repeated sex offenders, military institutions attempting to cover up reports of widespread harassment and assault, healthcare and law enforcement institutions neglecting trauma-informed practices for victims of sexual violence). Our hope is that this study encourages researchers and clinicians alike to look closely at traumatic events and attempt to disentangle interpersonal and institutional betrayal. Each may be occurring and if so, both are causing harm.

#### **Disclosure of interest**

Both authors have no financial conflicts of interests to report.

# Ethical standards and informed consent

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation [institutional and national] and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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