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Engagement of Sexual Violence Survivors in Research: Trauma-Informed Research in the THRIVE Study

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Abstract

Given the potential for retraumatization among survivors of sexual violence engaged in research, we aimed to provide pertinent knowledge and exemplification of the integration of trauma-informed practice to research with survivors. Grounded in trauma-informed care, we discuss the need for trauma-informed research, drawing upon experiences and data from a longitudinal case-control study on sexual violence. Through trauma-informed research settings, we can improve research experiences for survivors of sexual violence, as demonstrated by positive experiences of participants in The THRIVE Study. By meeting the needs of survivors, researchers can increase participation while maximizing the research quality and advancement of research.

Keywords

sexual violence, trauma-Informed care, trauma theory, sexual trauma, ethics

Introduction

Engagement of survivors of sexual violence in research is vital to continued progress toward understanding the acute and chronic impacts of sexual violence. Yet, survivors' participation in research may warrant unique considerations, particularly given growth

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in understanding of the experiences of survivors of trauma in health care and as research participants in recent years (Campbell et al., 2010; Carlson et al., 2003; Cromer et al., 2006; Deprince & Freyd, 2004; Jaffe et al., 2015; Sikweyiya & Jewkes, 2012). This includes the increased understanding of the physiological and psychological ramifications of trauma throughout the lifespan, the needs of survivors following violence, and the potential for revictimization. At its core, research, medical, and public health services require iterative consideration for the safety and well-being of participants and patients, and the standard of beneficence to which researchers and practitioners are held should continue to be heightened as the understanding of the needs of participants and patients grows. With this in mind, practitioners have developed "trauma-informed care" (TIC) or "trauma-informed practice," in which the experiences of patients are taken into consideration and adapted to, in order to account for the lasting impacts of trauma (Reeves, 2015). Integration of such practice in medical care and other support services allows for higher quality care and better health outcomes (Kelly & Garland, 2016; Reeves, 2015; Scheer & Poteat, 2018; Wilson et al., 2015). It is likewise necessary to reconsider the interactions of trauma survivors with research, and the obligation to undertake research that is trauma-informed. Resultingly, the aims of this paper are (a) to discuss the need for TIC in research interactions with survivors of trauma, and specifically survivors of sexual violence; (b) present and discuss the results of extensive trauma-informed protocol development and implementation (trauma-informed research [TIR]) for engaging survivors of sexual violence in research through the lens of The THRIVE Study, a biobehavioral study of survivors of acute sexual violence; and (c) present and discuss the results of an endline "Exit Survey" to evaluate the experience of participants with a history of sexual violence over their enrollment in The THRIVE Study.

Trauma and Sexual Violence Trauma

Individuals who experience traumatic events, including elder abuse, domestic violence, sexual abuse, ethnoviolence, and combat trauma, among others, may experience long-term adverse physical and psychological effects (Helms et al., 2012; Raja et al., 2015; Tansill et al., 2012; Thoits, 2010).

Survivors of trauma have more frequent interactions with health care systems due to the morbidities associated with trauma (Reeves, 2015). At each interaction with the health care system, trauma plays a role in an individual's engagement and experiences with health care, particularly in respect to the potential for retraumatization (Raja et al., 2015; Reeves, 2015). Retraumatization in this context is defined as "a process of reexperiencing traumatic stress as a result of a current situation that mirrors or replicates in some way the prior traumatic experiences (e.g., specific smells or other sensory input; interactions with others; response to one's surroundings or interpersonal context, such as feeling emotionally or physically trapped)" (Substance Abuse and Mental Health Services Administration [SAMHSA], 2014b, p. xviii). Fear of retraumatization may cause health care avoidance among survivors of trauma, and exacerbate negative psychological states associated with seeking care (Reeves, 2015).

In the United States, sexual violence continues to be a pervasive traumatic experience. According to the 2011 National Intimate Partner and Sexual Violence Survey, approximately 20% of U.S. women have experienced an attempted or completed rape within her lifetime. Far more- approximately 44%- experienced other forms of sexual violence, including sexual coercion and unwanted sexual contact (Breiding et al., 2014). In reality, these national statistics likely underestimate the true prevalence of sexual violence. Community samples report significantly higher rates, particularly for women of color (Basile et al., 2015, 2016; Cavanaugh et al., 2014; Draughon et al., 2014; Hazen & Soriano, 2007; Stockman et al., 2014). Young women are likewise at higher risk, with 40% of first rapes occurring before the age of 18, and 79% before the age of 25 (Breiding et al., 2014). Women with these experiences are also at high risk for repeat victimization, with research suggesting that two out of three individuals who experience sexual violence will be revictimized (Classen et al., 2005). Particularly at-risk populations include sexual minority men and women (López & Yeater, 2018; Walters et al., 2013) and trans or gender non-conforming individuals (James et al., 2016; Matsuzaka & Koch, 2018), who face increased rates of violence compared to their heterosexual and cisgender counterparts. While the burden of sexual violence among men in the United States is notably lower than among other groups, approximately 2% have experienced attempted or completed rape, and 23% have experienced non-rape sexual violence, with young men and racial and ethnic minority men at higher risk (Breiding et al., 2014).

People who have experienced trauma from sexual assault report significantly worse psychological and psychopathological outcomes compared to those without experiences of sexual assault, those without experiences of trauma, and those with experiences of non-sexual assault trauma (Dworkin et al., 2017). Such outcomes include worse post-traumatic stress disorder, depression, suicidal ideation and attempts, mood disorders, obsessive-compulsive conditions, and substance use disorders (Dworkin et al., 2017). Compounding this, the potential for retraumatization in the context of clinical care settings is of particular concern for survivors of sexual violence (Reeves, 2015). In health care and clinical research settings, in which survivors of violence may be asked to undergo physical examinations, including of the genitals, retraumatization can occur. Furthermore, the interpersonal dynamics of a physical exam may unknowingly employ similar tactics to those of an abuser, including being told to relax, or being made to feel restrained (Reeves, 2015). The potential for retraumatization is being increasingly, though insufficiently, addressed in clinical health care settings (Becker-Blease, 2017; Reeves, 2015).

TIC

Due to the adverse effects of trauma and potential for retraumatization, practitioners in recent years have begun to implement the principles of "TIC" or "trauma-informed practice." TIC is derivative of Trauma Theory, which postulates that traumatic experiences that are not processed will manifest physiologically (van der Kolk, 1994). Physiological alterations may occur in response to stimuli both associated and

unassociated with the original trauma and may be difficult to identify or anticipate (van der Kolk, 1994). Responsively, elements of a trauma-informed approach in health and social service systems have been defined by the SAMHSA. The SAMHSA guidelines include: (a) realizing the widespread impact of trauma exposure, (b) identifying how trauma may impact patients, families, and staff in this system, (c) responding by applying this knowledge into practice and institutional policies, and (d) preventing retraumatization (Center for Substance Abuse Treatment (US), 2014; SAMHSA, 2014a). These practices have been employed increasingly in recent years in clinical and support service contexts (Becker-Blease, 2017; Reeves, 2015), and contextually tailored frameworks to aid in the operationalization of TIC have been developed, including by Elliot et al. (2005).

Elliot and colleagues presented a framework for application of TIC with women who have experienced trauma and co-occurring disorders (2005). Specifically, the authors propose principles of TIC be operationalized in interactions with survivors of trauma, including: (a) recognize the impact of violence and victimization on development and coping strategies; (b) identify recovery from trauma as a primary goal; (c) employ an empowerment model; (d) strive to maximize survivor's choices and control over their recovery; (e) frame the researcher–participant relationship as a relational collaboration; (f) create an atmosphere that is respectful of survivor's need for safety, respect, and acceptance; (g) emphasize survivors' strengths, highlighting adaptations over symptoms and resilience over pathology; (h) minimize the possibilities of retraumatization; (i) strive to be culturally competent and to understand survivors in the context of their life experiences and cultural backgrounds; and (j) solicit participant input on the research process and involve participants in various stages of research (Elliot et al., 2005).

In 2019, Campbell et al. brought attention to the lack of application of TIC to research on sexual violence, particularly in a systematic manner, and built upon the principles of TIC proposed by Elliot et al. in 2005. They highlighted the need to transition from research on TIC to research *utilizing* TIC, and called for researchers to shift to integration of trauma-informed principles into research practice (Campbell et al., 2019). This call echoes and urges operationalization based on the wealth of research available on the positive impact of trauma-informed services both generally and among survivors of sexual violence (Kelly & Garland, 2016; Reeves, 2015; Scheer & Poteat, 2018; Wilson et al., 2015). Survivors of violence who perceived greater application of TIC in their services report more empowerment and emotional regulation, and lower social withdrawal, which in consonance with lower shame lead to better mental and physical health outcomes (Scheer & Poteat, 2018). Likewise, interventions have successfully employed tenants of TIC to improve participant health outcomes among female survivors of interpersonal violence (Kelly & Garland, 2016). As such, the use of trauma-informed principles in research settings with survivors of violence should be strongly considered, as should the systemic application thereof.

Approaches have been suggested for the engagement of survivors of sexual violence in research, with an emphasis on qualitative or survey research, including the employment of feminist research methods, such as active listening and the

establishment of trust in the relationship between a participant and researcher (Campbell et al., 2009, 2019). However, to our knowledge, no literature has been published on the operationalization of principles of TIC in a clinical research setting, and particularly to biobehavioral research inclusive of invasive clinical health care examinations. Given this gap, we seek to describe and discuss the application of principles of TIC to a clinic-based biobehavioral research study on susceptibility to HIV among acute cisgender female survivors of sexual violence.

Method

The THRIVE Study

The THRIVE Study is a longitudinal case-control study of adolescent girls and women between the ages of 14 and 45, living in San Diego County, California. Detailed methods of The THRIVE Study have been previously described (Stockman et al., 2020). In brief, The THRIVE Study aims to understand the association between sexual violence and HIV acquisition through direct and indirect pathways. These pathways include disruption of physical barriers in the cervical-vaginal environment and associated inflammation, or alterations to hormonal pathways controlling immune reactions in the vaginal environment and systemically. These pathways may allow for increased ease of HIV infection upon exposure (Campbell, Baty, et al., 2008). Additional factors may increase HIV susceptibility in adolescent girls, such as immaturity of the cervical-vaginal environment, high STI incidence and prevalence, and hormonal fluctuations due to irregular menstrual cycles (Ghosh et al., 2018). Women are recruited for The THRIVE Study through community organizations, a local rape crisis center, and utilizing physical flyers in community locations and social media advertisements. Women who are eligible to enroll in The THRIVE Study have experienced either consensual vaginal sex with a male partner within the last month (controls), or forced vaginal penetration perpetrated by a male within the last month (cases) (both criteria expanded from two weeks in initial study development). The THRIVE Study is enrolling 120 girls and women, with 30 participants enrolled in each of the following categories: adolescent controls (aged 14–19), adult controls (aged 20–45), adolescent cases (aged 14–19), and adult controls (aged 20–45). Women of all backgrounds are eligible to participate; however, recruitment strategies emphasize populations underrepresented in sexual violence research. Women interested in assessing their eligibility can contact study staff through email, phone call, or text message. Potential participants are informed of the purpose of the study, study procedures, and risks and benefits; those who provide consent to be screened are given the option of screening over the phone with a study staff member, or self-completing a digital screener. For participants who choose to enroll, after providing written informed consent, women attend a series of three study visits over the course of three months; at each they are asked to complete an interviewer-administered survey, undergo a blood draw, and receive a cervicovaginal exam including the collection of vaginal swabs for reproductive tract infections (including sexually transmitted infections) and collection of

cervicovaginal lavage (CVL) fluid, used to assess immune alterations in the vaginal environment. Participants then self-collect three saliva samples a day for three days, to assess the cortisol awakening response (CAR). Participants are provided with $50 in compensation for each in-person study visit, and $35 upon receipt of the at-home saliva samples, for total compensation up to $255. Additionally, all participants receive information on local free or low-cost medical and social services and resources, as well as individualized counseling on resources of interest to the participant. To facilitate enrollment and retention, participants are provided with transportation assistance in the form of either a public transportation day pass or complimentary rides to and from study visits through a rideshare service. Saliva samples are picked up from participants at a location of their choice. All procedures are approved by the University of California San Diego Institutional Review Board.

Operationalization of TIR

Prior to study implementation, we undertook the development of expansive protocols and trainings to operationalize TIR in The THRIVE Study. To illustrate the use of these protocols, and demonstrate a systematic application of principles of TIC to research, we utilized the same principles of trauma-informed services for women proposed by Elliot et al. (2005), in coordination with the suggested interpretation of each principle suggested by Campbell et al. (2019), and employing tactics derived from feminist research methods (Campbell et al., 2009, 2019). These protocols include precautions and safety planning throughout every element of The THRIVE Study to maximize participant choice and control, emphasize empowerment and validation of experiences, provide services and referrals to the extent possible for a non-intervention research study, and avoid retraumatization of women choosing to participate. Protocols were developed in coordination with research team members who identify as survivors of sexual violence, and revised based on review by survivors and survivor advocates at a local rape crisis center.

The THRIVE Study Exit Survey

Participants enrolled in The THRIVE Study are given the opportunity to complete an optional "Exit Survey" following completion of their participation. The exit survey captures participants' experiences with recruitment and participation in the study and is completed through an online survey on REDCap. Participants provide consent, complete the survey, and receive $5 compensation for their time. Regarding participation in the study, three questions are asked to assess experience with the current research: (a) How did you feel about your participation in The THRIVE Study? (Very Positively, Somewhat Positively, Neither Positively or Negatively, Somewhat Negatively, Very Negatively); (b) How did your participation in The THRIVE Study compare to your participation in other research studies (Much Better, Somewhat Better, Neither Better or Worse, Somewhat Worse, Much Worse); (c) Did participating in The THRIVE Study change how likely you are to

participate in other research studies? (Yes, More Likely to Participate, Yes, Less Likely to Participate, No, Did Not Change). Finally, participants were provided with space to provide qualitative explanation for their ratings, what they liked about participating in The THRIVE Study, and what they did not like about participating in The THRIVE Study. For analytic purposes, we classified women as having had a past-month experience of forced or threatened vaginal penetration perpetrated by a male ("case" participants), having experienced a pressured, threatened, or forced first sexual experience (nonconsensual sexual debut; among case participants, no past-month experience of sexual violence was a first sexual experience/sexual debut), and having ever experienced sexual violence (inclusive of the two former categories).

Results

Protocols created for The THRIVE Study were mapped onto the framework developed by Elliot et al. (2005) with the description of each principle provided by Campbell et al. (2019) in Table 1. Protocols considered to be standard practice are denoted "SP," contrasted with protocols considered to be additionally trauma-informed, denoted "TIR."

Quantitative findings from the Exit Survey are presented in Table 2, and contextual qualitative findings presented in Table 3. Of all participants invited ($N = 64$; of 67 total participants, 3 were administratively withdrawn, 1 is actively enrolled), 40 participants completed the Exit Survey (61.5%). Exit Survey respondents were racially and ethnically diverse, with a mean age of 25.6 (SD: 7.7). Participants reported that they felt very positively about participation in The THRIVE Study (89.5%), that participation in The THRIVE Study was a better experience than other studies they had participated in (87.5% among those with previous study experience), and that they are more likely to participate in other research studies after partaking in The THRIVE Study (85.0%).

These results were mirrored among women who had experienced sexual violence. Among survivors of recent sexual violence ("cases"), over 90% felt positively about their experience, while the same was said by almost 95% of women who experienced a nonconsensual sexual debut (pressured, threatened, or forced first sexual experience), respectively. No past-month experience of sexual violence was reported to be a first experience of sexual violence; therefore, these groups are neither mutually inclusive nor mutually exclusive. Among women who had ever experienced nonconsensual sexual activity, 90.5% felt positively. Similarly, cases, survivors of nonconsensual sexual debut, and survivors of forced sexual activity endorsed that participation in The THRIVE Study was better than participation in other studies and shared that they are more likely to participate in other research because of their experience in The THRIVE Study. Notably, no participants responded that they had a negative experience while enrolled in The THRIVE Study, that their participation in The THRIVE Study was worse than their participation in other studies, or that they were less likely to participate in other research due to their participation in The THRIVE Study.

Table 1. Principles of Trauma-Informed Care and Their Application in Trauma-Informed Research.

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
1. Recognize the impact of violence and victimization on development and coping strategies.	Be aware that interpersonal violence and child abuse have ongoing negative impacts. Trauma affects many aspects of a person's identity, relationships, worldview, and coping behaviors.	Interviewers are prepared to hear all experiences during data collection. With exceptions for specific survey questions, participants are not probed or asked to elaborate on experiences. (TIR) Interviewers are prepared to provide referrals and warm handoffs to services or crisis intervention, and a Licensed Therapist is available for crisis counseling. (TIR) Interviewers check in with participants to allow for alteration to study visit flow, breaks, or adaptation to promote coping. (TIR)
2. Identify recovery from trauma as a primary goal.	Provide trauma-specific resources to aide in survivors' recovery.	All participants are provided with information about a wide variety of free or low-cost local and national social and medical services. (SP) Interviewers provide resource counseling, including referrals and warm handoffs to services that participants express interest in, or which may be relevant based on history conferred during the study visit. (TIR)
3. Employ an empowerment model.	Give participants choice and control over their actions. As a researcher, engage in a partnership with the participant in which each person's knowledge is valued.	Recruitment materials clearly state experience of sexual assault as an eligibility criterion, ensuring transparency. (SP) During recruitment procedures, study staff disclose all elements of the study to potential participants, including what makes them eligible for the study, if forced vaginal penetration.

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		Study staff confirm with the participant that they understand all elements included in the study, and specifically the vaginal exam. (SP) Participants are given the option of bringing a support person with them to their visit (friend, family, survivor advocate, etc.). (TIR) Participants are thanked for being willing to participate in research at the beginning of study, with acknowledgement of the impact their contribution can make. (SP) Informed consent is carried out through verbal explanation and review of the informed consent documentation by the interviewer, with check-ins for comprehension, and discussion of any questions the participant may have. (SP) During the informed consent process, the potential benefits of their contribution to the research are discussed, as well as the potential benefits and risks to the participant. (SP) At the beginning of study visits, interviewers describe the study visit process to participants (SP), and ask for feedback on if the study visit "plan" for the day is acceptable. (TIR)
4. Strive to maximize survivor's choices and control over their recovery.	Provide participants with choices, options, and a sense of control over decision in the research process.	Interviewers check in with participants regularly to allow for alteration to clinic visit flow, breaks, or adaptation to promote coping (e.g., Are you comfortable doing the blood draw next?). (TIR)

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		Participants are regularly reminded of what is coming next within a data collection section (e.g., During survey, "Next I have a few questions about what you experienced last week." During vaginal exam, "Next I am going to put my hand on your leg."). (TIR) Participants are given control over elements of the study visit, including termination or skipping visit elements. This includes any questions a woman does not want to answer, or any biological sample collections she does not want to complete. (SP) Participants are reminded of this regularly, and specifically before sensitive data collection, such as questions about sexual violence and the vaginal exam. (TIR) During survey and biological specimen collections, particularly the vaginal exam, participants are given options on how they would like to have it conducted. (e.g., During vaginal exam, "Would you like to insert the speculum yourself, or would you like me to insert it?") (TIR)
5. Frame the researcher–participant relationship as a relational collaboration.	Recognize and aim to reduce the power imbalances in the researcher–participant relationship.	Interviewer emphasizes that the needs of the participant come first, not data collection. (TIR) Participants are informed that they will receive compensation for time and travel and transportation assistance for a visit even if they

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		decide not to complete the visit once arriving. (SP) Participants are regularly asked to check in on how they are feeling, and consider if they want to continue with the research study visit. (TIR) Number of study staff participants interact with is limited to facilitate building of relationships and reduction of power imbalances. (TIR)
6. Create an atmosphere that is respectful of survivor's need for safety, respect, and acceptance.	Strive for comfort, privacy, and psychological and physical safety in the research space. Protect participant confidentiality and provide clear information about role and expectations.	Study screening for case eligibility includes open-ended questions for survivors to describe their experience in their own words, rather than assignment of labels for their experience by study staff (ex. "rape,"). Broad, widely used terms are used for recruitment (i.e., "sexual assault") rather than specific terms to allow for participants to conceptualize their experience independently. Study staff classify eligibility or request additional information based upon these descriptions. (TIR) Study visits are conducted in an outpatient research clinic not connected to the hospital on a university hospital medical campus, allowing for institutional validation of the study, a location external from any hospital or any sexual assault response team (SART) services, and a location *only* used for research, so that participants do not interact with staff that may

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		provide them with routine care. (TIR) Participants are provided with free transportation assistance in the form of a study-paid rideshare service. (SP) Participants are informed that they can be picked up or dropped off at any location to ensure security, that they may use a pseudonym to protect their identity, are provided the information regarding the ride and driver directly to their indicated mobile device, and that study staff are able to see the driver information and location of their driver at all times during the ride through the rideshare platform to ensure safety. (TIR) Clinic staff are present at a front desk at all times during clinic hours, allowing for security for participants. (SP) Participants are asked if they have preferences for contact procedures by study staff, including method of contact or any safety rules. (TIR) All participants are informed that biological samples are sent for testing de-identified with only a participant identifier number. (SP) All participants are informed that the research clinic does not operate within the university medical record system due to participant sensitivity, allowing for no record of study visits external from the clinic. (SP)

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		Interviewers use the language identified by the participant when referring to the incident(s) of sexual violence during the study visit. (TIR)
7. Emphasize survivors' strengths, highlighting adaptations over symptoms and resilience over pathology.	When appropriate, use the term survivor rather than victim, which can carry connotations of powerlessness. Validate survivor's resilience, recognizing that trauma symptoms may come from survivor's efforts to cope with the trauma.	All language within study visits is framed using survivor-centered messaging, rather than victim-centered messaging. (TIR) Interviewers practice active listening during study visits to confer empathy. (TIR) Interviewers integrate validation of participants' experiences and feelings, with the exclusion of behavior harmful to the survivor or others. (TIR) Study physician and nurse practitioner ask participant how much they would like to know regarding the vaginal exam and pathology, and accommodate the requested level of information. (SP)
8. Minimize the possibilities of retraumatization.	Recognize ways in which the research may be retraumatizing. Avoid intrusive or insensitive research procedures that could trigger trauma-related symptoms.	Interviewers discuss the possibility of retraumatization with participants during informed consent discussion. (SP) Interviewers notify participants prior to study visit elements or survey questions that may be triggering and remind participants that they can skip any study element or take a break at any time. (TIR) Interviewers only ask a few, specific questions about participants' recent experience with

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		sexual violence. Interviewers do not probe beyond these questions. (TIR) Participants are asked to provide feedback on their participation in the study following completion of all study visits, to allow for iterative review of trauma-informed procedures. (TIR)
9. Strive to be culturally competent and to understand survivors in the context of their life experiences and cultural backgrounds.	Develop the knowledge and skills needed to understand participants' cultural contexts. Consider how participants' identities and backgrounds interact with their trauma. Recognize that different cultures have different ways of conceptualizing and healing from trauma.	Recruitment and informed consent procedures are designed to facilitate utmost transparency (SP), particularly with consideration for medical mistrust. (TIR) Study materials and procedures are reviewed by (a) a Center for AIDS Research Community Advisory Board focused on Health Equity, to ensure appropriateness of content for women from diverse backgrounds and conceptualizations of health; (b) survivors of sexual violence on the study team, to understand differing reactions to the study materials and procedures; and (c) sexual assault victim advocates from a local rape crisis center, to capitalize on the advocates' knowledge and experience working with diverse survivors of sexual violence. (TIR) Recruitment efforts utilize both advertisements targeted to any eligible woman, specifically not including any imagery of woman to avoid racial/

(continued)

Table 1. (continued)

Trauma-informed principle (Elliot et al., 2005)	Description of principle (Campbell et al., 2019)	Examples of application in The THRIVE Study
		ethnic bias, as well as advertisements specific to girls and women of color, developed in coordination with community members of diverse backgrounds. (TIR) All study staff are trained in cultural contextualization of sexual violence. (TIR)
10. Solicit participant input on the research process and involve participants in various stages of research.	Consider ways that participants can be involved in the research process, such as using participatory research methods or forming survivor research advisory boards.	Participants are asked to provide feedback on their participation in the study informally throughout the study, as well as following completion of all study visits through an "Exit Survey," to allow for iterative review of trauma-informed procedures. (TIR)

Table 2. The THRIVE Study Exit Survey Quantitative Results.

		Case/control status, *N* (%)		Nonconsensual sexual debut, *N* (%)		Ever experienced forced sex, *N* (%)	
	All, *N* (%)	Case	Control	Yes	No	Yes	No
How did you feel about your participation in The THRIVE Study? (*N* = 38)							
Very positively	34 (89.5)	12 (85.7)	22 (91.7)	17 (89.5)	17 (89.5)	18 (85.7)	16 (94.1)
Somewhat positively	2 (5.3)	1 (7.1)	1 (4.2)	1 (5.3)	1 (5.3)	1 (4.8)	1 (5.9)
Neither positively nor negatively	2 (5.3)	1 (7.1)	1 (4.2)	1 (5.3)	1 (5.3)	2 (9.5)	0
Somewhat negatively	0	0	0	0	0	0	0
Very negatively	0	0	0	0	0	0	0
How did your participation in The THRIVE Study compare to your participation in other research studies? (*N* = 40)							
Much better	14 (34.0)	4 (26.7)	10 (40.0)	9 (45.0)	5 (25.0)	6 (28.6)	8 (42.1)
Somewhat better	7 (17.5)	1 (6.7)	6 (24.0)	0	7 (35.0)	2 (9.5)	5 (26.3)
Neither better nor worse	3 (7.5)	1 (6.7)	2 (8.0)	2 (10.0)	1 (5.0)	3 (14.3)	0
Somewhat worse	0	0	0	0	0	0	0
Much worse	0	0	0	0	0	0	0
First research study	16 (40.0)	9 (60.0)	7 (28.0)	9 (45.0)	7 (35.0)	10 (47.6)	6 (31.6)
Did participating in The THRIVE Study change how likely you are to participate in other research studies? (*N* = 40)							
Yes, I am more likely to participate.	34 (85.0)	14 (93.3)	20 (80.0)	18 (90.0)	16 (80.0)	20 (95.2)	14 (73.7)
Yes, I am less likely to participate.	0	0	0	0	0	0	0
No, did not change.	6 (15.0)	1 (6.7%)	5 (20.0)	2 (10.0)	4 (20.0)	1 (4.8)	5 (26.3)

Table 3. The THRIVE Study Exit Survey Qualitative Results.

Please explain your evaluation of your experience in The THRIVE Study
"The experience seemed better than a normal doctor visit. It was an open environment." ("Control" Participant)
"Friendly staff, personal nature - I just liked your study a lot and felt like it benefited me too." ("Control" Participant, Survivor)
"THRIVE made participating in a study feel easy and convenient. They motivate me to participate in other studies to help further research for other vulnerable populations." ("Control" Participant)
"When I answered questions regarding suicidal thoughts the THRIVE study workers I was with took time to offer me information, pamphlets, and themselves as sources of contact. I appreciated the time and effort put in by the workers." ("Control" Participant)
"I was treated with such respect and I also never felt like I was being judged by the responses I would give." ("Control" Participant, Survivor)
"Now I'm more likely [to] do mental health studies and not try [to] cheat from fear." ("Case" Participant, Survivor)
"Everyone made me feel very comfortable and safe. Very professional and centered around women." ("Control" Participant, Survivor)
"[The study team] were patient and soft with me, they were supportive when I had a trauma response. They always made me feel comfortable and ensured I was ready/at ease. It's easy to participate in a study, when the people you're working with from blood draws to exams to online surveys, have your best interest." ("Case" Participant, Survivor)
"Your study gave me the courage to leave a very unhealthy relationship." ("Case" Participant, Survivor)
How did you feel about participating in The THRIVE Study?
"The people involved in performing the study were very sweet and they made it feel like an open space." ("Control" Participant)
"The coordinators were very friendly and I felt comfortable answering their questions. They felt like sisters I could confide in!" ("Control" Participant)
"I felt like it was a very positive experience and the people I met were very accommodating. I also really appreciated receiving a call from the doctor when a test came back positive. She was so supportive and I felt like I could reach out to her anytime." ("Control" Participant, Survivor)
"Everyone was completely positive, confidential, and professional. Everyone was so nice and kind and approached everything in a way that made me completely comfortable. They were concerned about me the whole time and made me feel good. They even accommodated my transportation and took into consideration everything that might have been an inconvenience." ("Case" Participant, Survivor)
What did you not like about participating in The THRIVE Study?
"It was sort of far for me, making it a bit hard to schedule time for me to make such a long trip." ("Control" Participant, Survivor)
"Vaginal exams aren't fun and neither is getting your blood drawn." ("Control" Participant, Survivor) "Not a big fan of the saliva sampling." ("Control" Participant)
"It was a bit confusing, but that was mainly due to the COVID crisis. I'm sure under better circumstances it would've been more organized. It was also emotionally very difficult at times." ("Case" Participant, Survivor)
"The questions were still uncomfortable but I know it was part of the process." ("Case" Participant, Survivor)
"Vaginal exam, but it went as well as it possibly could because of the doctor." ("Case" Participant, Survivor)

Discussion

The present article provides review of the need for integration of TIC into research with survivors of sexual violence, as well as the methodological process of operationalizing TIC in biobehavioral research, and evidence of the positive experiences of survivors of sexual violence during their participation. Such an example may provide insight and guidance for the operationalization of trauma-informed practices in other research studies. While the current application is in regard to survivors of sexual violence, TIR could be operationalized in the context of research with survivors of any type of trauma, given adequate consideration for trauma-specific sequelae. Similarly, subgroups of survivors of trauma, including racial and ethnic minorities, may be well served by appropriately culturally adapted TIR.

Acceptability of Research with Survivors of Sexual Violence

Engagement of survivors of sexual violence in research has prompted prior discussion given the sensitivity of populations and invasiveness of research (Burke Draucker, 1999; Jaffe et al., 2015). There is ample evidence for the acceptability of engagement in research for trauma survivors (Griffin et al., 2003), and research has found that survivors of sexual violence who participated in research on the topic reported benefits from their participation (Campbell, Adams, & Patterson, 2008; Campbell et al., 2009, 2010; Jaffe et al., 2015). This acceptability is echoed in the current THRIVE Study Exit Survey findings, with the vast majority of participants, both survivors of sexual violence and women who have not experienced forced sex, endorsing their experience as very positive. Previous research found that participants who did not benefit from research participation typically did not experience any additional distress, or only experienced small amounts of non-extreme distress (Campbell, Adams, & Patterson, 2008; Campbell et al., 2009; Carlson et al., 2003; Deprince & Freyd, 2004; Jaffe et al., 2015; Sikweyiya & Jewkes, 2012). This too is supported in the current findings in that no participants reported negative experiences, and fewer than 10% of participants with experience of forced sexual activity had a neutral experience. Engagement of survivors in the *acute* aftermath of trauma has also been found acceptable to research participants (Griffin et al., 2003). Indeed, "case" participants in The THRIVE Study reported positive experiences, and an increased likelihood of participating in other research studies. Even with the possibility of distress caused by participation, trauma research has found that participants perceive research on their traumatic events to have greater importance and a greater cost–benefit ratio compared to research on other topics (Cromer et al., 2006; Deprince & Freyd, 2004), consistent with our qualitative findings. While participants acknowledged discomfort (both emotional and physical), but at an acceptable level, as two "case" participants noted: "The questions were still uncomfortable but I know it was part of the process" and "[the] vaginal exam [was uncomfortable], but it went as well as it possibly could because of the doctor."

Despite the wealth of previously published research and the current findings, there may be unknown risks to survivors of sexual violence during engagement with

Table 4. Lessons Learned in The THRIVE Study: Comparison to Standard Practice and Application Within the Research Process.

Lesson learned	Standard practice	Trauma-informed practice	Research process application
Training of study staff	Ethical conduct of research/human subjects research training (i.e., CITI)	Ethical conduct of research/human subjects research training (i.e., CITI); mental health first aid training; trauma-informed care training; study procedure training series	Grant writing; development of standard operating procedures/protocols; time allocation and budgeting for research staff; recruitment; study implementation/ data collection
Preparation for connection to support services	Provision of national or local hotline numbers (411, National Suicide Hotline, local crisis line)	Provision of national or local hotline numbers (411, National Suicide Hotline, local crisis line); provision of name and telephone number of specific local organizational contact; request permission to given contact the participant's information to facilitate follow-up	Grant writing (letters of support); development of standard operating procedures/protocols; dissemination of study information and engagement of community stakeholders and support services
Participant engagement	Neutrality in study procedures and data collection	Employment of feminist research methods in study procedures and data collection; leading with compassion in participant interactions	Development of standard operating procedures/ protocols; hiring of research staff; recruitment; study implementation/data collection

research that impact acceptability. Additionally, given the diversity of survivor experiences, risks and perceived risks may be variable among participants. Particularly, the difficulties of participating and the risk of retraumatization may not outweigh the perceived benefit of contribution for a given participant. As such, it is the imperative for the researcher to allow for individual choice in research participation, in which each potential participant conducts their own perceived risk-benefit assessment. This requires the minimization of coercion financially or from interpersonal sources. Furthermore, transparency and openness regarding the research process and the role of participants are vital to an informed decision about participation, including not only the informed consent process, but repeated check-ins and repetition of participant

rights. This served as a guiding principle in the operationalization of TIR in The THRIVE Study, to protect individual choice.

The theorized operationalization of TIR requires the expansion of the role of researcher to encompass provision of validation to participants, with understanding of their trauma history and ramifications of those experiences, such as through active listening (Campbell et al., 2019). Feminist research methods have long advocated that expressions of empathy and humanity are within the bounds of the researcher (Corbin & Morse, 2003; Janice et al., 2008). In previous research, survivors have indicated that such methods are appreciated and create a more positive experience (Campbell et al., 2009); these sentiments were reflected in the qualitative findings from the Exit Survey. As a "control" participant stated, "The coordinators were very friendly and I felt comfortable answering their questions. They felt like sisters I could confide in!" However, there remain concerns that expansion of the traditional research role could introduce bias in results, which traditional research methods have sought to avoid by having interviewers remain neutral.

Given the sensitivity of the topic of sexual violence, and stigma associated with it, underreporting is a persistent problem faced by researchers. Validation, acceptance, and empathy of experiences of sexual violence could create a social desirability bias toward disclosure of events of sexual violence, regardless of actual experience, overestimating the reported burden of sexual violence. However, reporting of events that have not happened is rare (Ferguson & Malouff, 2016), while reporting of events that have happened is thought to be well below the actual incidence and prevalence, due to persistent stigma, mistrust of establishments, fear, lack of acknowledgement by the survivor, and difficulty of measurement (Bagwell-Gray et al., 2015; Cohn et al., 2012; Wilson & Miller, 2015). As such, it is unlikely that any pro-reporting bias due to a small number of individuals misreporting experiences of sexual violence would correct beyond the anti-reporting bias due to the vast number of women *not* reporting true events.

Of further benefit and importance, the practices of active listening, establishment of trust, and empathy may serve to increase reporting even external from research, by challenging the common social desirability bias that pushes toward practices of nonreporting (Bagwell-Gray et al., 2015; Cohn et al., 2012; Wilson & Miller, 2015). Such bias is evidenced by the low prevalence of reporting and service-seeking postsexual violence (Amstadter et al., 2008; Campbell et al., 2001; Ullman, 1996, 2007; Ullman & Filipas, 2001). A neutral response from interviewers may serve to reinforce a perceived societal stigma against that experience and affirmative response, promoting underreporting. Validation of experiences impresses upon participants the acceptability of an affirmative response and may decrease underreporting; these approaches have also been suggested for use with survivors of sexual violence previously (Campbell et al., 2009, 2019). As one "case" participant noted, after participation, "Now I'm more likely [to] do mental health studies and not try [to] cheat from fear." Given these considerations, departure from traditional "neutral" research methods was judged acceptable in the operationalization of TIR, and feminist research methods were used as a guiding model.

Finally, the application of TIR demonstrates how research stands to benefit greatly from the integration of principles of TIC. Qualitative work has suggested that survivors of sexual violence may be more willing to participate in research when they are cared for and their needs are met through that research (Campbell et al., 2010). It logically follows that they may also be more likely to share these positive experiences, leading to increased recruitment from their social networks and communities. Participant reengagement, as well as assistance in recruitment of other survivors through social networks, is highly valuable given the documented difficulties of recruiting sensitive populations such as survivors of sexual violence (Campbell et al., 2010; Edwards et al., 2014; Gidycz et al., 2008). Additionally, prevention of retraumatization (Reeves, 2015) and more positive experiences attributable to trauma-informed and feminist practices (Campbell et al., 2009) may increase retention in research with sensitive populations (Daykin et al., 2018), which is a noted difficulty (Campbell, Adams, & Patterson, 2008). The THRIVE Study exemplifies this. To date, the study has retained 92.0% of "case" participants (data not shown). Displays of empathy and understanding associated with TIC may contribute to more trust in the researcher-participant relationship (Campbell et al., 2019; Elliot et al., 2005), possibly allowing for increased ease of disclosure of trauma and more accurate reporting rates from participants. This may also be extrapolated to the larger population of research participants, who may also benefit from and find more acceptable a paradigm of TIR. Of vital importance is the recognition that researchers need participants in order to gather data to inform intervention and program efforts to better serve survivors of violence and trauma. Those with negative experiences or neutral experiences in research may be less likely to engage with studies, much as trauma survivors may avoid health care (Reeves, 2015). Logically, the opposite may also be true; when survivors have positive experiences in research, they may be more likely to participate in other research. Among participants in The THRIVE Study, this was found to be correct and impactful. Compared to their "non-exposed" counterparts, survivors of sexual violence were more likely to report an increased likelihood of future study participation, across survivorship categories.

Lessons Learned

The experience of developing and implementing protocols for potentially invasive research with survivors of sexual violence was undertaken in an intentionally iterative manner, as the research team learned how to better engage and support participants. While protocols were developed in consultation with survivors of sexual violence and survivor advocates, we could not anticipate all needs and best practices, and we learned valuable lessons from our participants (Table 4). Two elements of the protocol were found to be vital to appropriate engagement with survivors. The first of these was intensive training of staff members interacting with participants. In addition to ethics and good conduct of research training, staff members completed a multi-day course on Mental Health First Aid, seminar-style training on TIC, thorough review of written protocols for the study, shadowed study visits conducted by a senior staff

member, and then conducted visits in the presence of a senior staff member for feedback and support. Only after the completion of this sequence were staff members scheduled for study visits one-on-one with participants. Information provided in this training series allowed staff members to reduce distress and streamline study activities for participants. Additionally, support was provided to staff to process their experiences with survivors.

Secondly, extensive preparation of resources and the ability to facilitate connections directly to individuals at support service organizations was essential for supporting survivors who enrolled in the study. Most survivors had not sought formal support after their sexually violent experience; this resulted in their study interaction being the first opportunity for them to be connected to support services. Needs were diverse, including housing support and nutritional support, in addition to connection to mental and physical health care. The preparation of documentation of available resources prior to the onset of the study, and having staff well acquainted with the resources, allowed for customized responsiveness to participants' needs. Furthermore, participants communicated appreciation for the provision of contact information for individuals at organizations, rather than general phone lines, reducing the need to navigate administrative pathways.

Even with these preparations, the research team learned repeatedly that the needs of survivors are diverse, and no individual reacts the same way to experiences of sexual violence. Acknowledging this, it became evident that the individuals conducting research, including investigators and staff, had to lead with compassion and understanding. No amount of training or ability to refer equated to a better experience for survivors, only a more informed experience. This is in line with approaches previously suggested for engaging survivors in research, including the use of active listening and building trust with participants (Campbell et al., 2009, 2019). Identifying staff members who were able to be respectfully, appropriately, and caringly responsive to all participants, and particular survivors of sexual violence, was paramount to the success of survivor engagement efforts.

Conclusion

The body of evidence of the positive impact of TIC throws into juxtaposition the possible negative effects of interacting with traditional care, and more pertinently, traditional research. Specifically, retraumatization and additional distress, though rare, may be caused by such participation (DePrince & Chu, 2008; Deprince & Freyd, 2004; Jaffe et al., 2015; Sikweyiya & Jewkes, 2012). As the field of trauma research discovers less harmful and non-harmful ways for survivors to participate in research, there is a risk of violating the standard of non-maleficence with the continuation of "traditional" and non-trauma informed methods as the standard of care. It is on this basis that health service fields have moved toward integration of TIC, and so too must health research. TIR is an avenue for this integration.

Given the significant need for the adoption of TIC in research settings that engage survivors of trauma and the increased potential for retraumatization associated with clinical research involving physical examinations, the current article demonstrates

the application of TIC to the clinical research setting, which we refer to as TIR. Without the participation of survivors of trauma in research, improvement of experiences, promotion of healing, and facilitation of prevention efforts cannot be accomplished. This underscores the necessity of awareness and promotion of survivor engagement and experience. Trauma-informed care is a method of doing so; as such, TIR is a path to better and continued research.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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