



Achieving Service Change Through the Implementation of a Trauma-Informed Care Training Program Within a Mental Health Service

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Abstract

As evidence continues to accumulate for the association between childhood trauma and long-term adverse outcomes, Trauma-Informed Care (TIC) approaches are emerging as fundamental to contemporary mental health services. To evaluate a workshop designed to influence mental health practitioners in TIC principles and practices. Nursing, medical and allied health professionals completed pre and post measures of confidence, awareness and attitudes towards TIC practice. The workshop was rated as highly relevant and useful to clinician's practice. Participants' self-reported confidence, awareness and attitudes towards TIC significantly increased ($p < .001$) and the perceived number of barriers to working within a TIC framework significantly decreased ($p < .05$). Child and Adolescent Mental Health clinicians routinely screened for trauma and 80% had received training in a trauma specific intervention at follow-up. This brief training provides an important foundation for the development of trauma-informed, evidence-based mental health services.

Keywords Trauma-informed · Trauma training · Mental health services · Implementation · Evaluation

In the context of increasing awareness of the pervasiveness of childhood trauma and its long-term impact (Felitti et al. 1998; Green et al. 2010; Lange et al. 1999; McLaughlin et al. 2010), there is a need to ensure that mental health systems are sensitive and responsive to the impact of trauma on those receiving services. The need for services to adopt a trauma-informed framework has been a major thrust in Australia by the Mental Health Coordinating Council (MHCC 2010, 2013) and by the USA based Substance Abuse & Mental Health Services Administration (2014). Trauma-informed organisations appreciate the high prevalence of trauma, its serious consequences, and the way trauma may

impact on people across their lifespan (Hodas 2006). Central to this is ensuring that clinicians understand the relationship between an individual's trauma experiences and their current symptoms and behaviours. Trauma-informed services are aware of the potential for traditional service delivery to re-traumatise individuals (Connors-Burrow et al. 2013) and the need to work compassionately and collaboratively with their clients so as not to reactivate their past experiences. Ensuring access to trauma-specific interventions or services is also a critical component of any therapeutic system (CATS Consortium 2007; Cohen and Mannarino 2008; Harper et al. 2008). According to Hanson and Lang (2016), Trauma-Informed Care (TIC) involves three primary domains: workforce development (training and awareness raising), trauma-focused services (standardised screening measures and evidence-based practices), and organisational practices (collaboration, service coordination, and clear policies).

Prior research has shown that although community mental health clinicians perceive trauma to be a significant adverse factor in their client's histories, they are reluctant to enquire about trauma, to routinely screen, diagnose or address their client's trauma symptoms (Frueh et al. 2002, 2006; Mueser et al. 1998; Salyers et al. 2004). According to Frueh et al.,

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“trauma has acquired a mystique that leaves clinicians fearful of addressing it” (2006). Others have suggested that the lack of attention to the field of traumatic stress in the undergraduate curriculum of most health professions has contributed to inadequately resourced services (Courtois and Gold 2009). In order to address this training gap, comprehensive training guidelines and specialised packages are being developed for use in a broad range of health settings (Courtois and Gold 2009). There is some emerging evidence indicating that a single-day TIC workshop is associated with improved communication skills in primary health professionals (Hall et al. 2016; Helitzer et al. 2011) and more positive perceptions by their patients (Green et al. 2016). Despite the growing popularity and dissemination of TIC training programs, the lack of evaluation data is a clear gap that needs to be addressed. Furthermore, research is also needed on the sustainability of staff practices over time following TIC training and education (Wilson et al. 2017). We report data on the results of a single-day TIC training, delivered to a range of health and mental health professionals in an Australian context. The study aimed to (i) assess whether participation in a single-day TIC workshop increases participants’ self-rated confidence, awareness and attitude towards working with clients with trauma histories and (ii) reduces participants’ perceived barriers towards working with such clients. We also aimed to qualitatively explore the most important clinical aspects of the workshop, participants intended changes to practice and further training needs. Lastly, we explored whether there was an increase in the participants interest in, and readiness for, training in trauma-specific interventions.

Background

Mental Health, Justice Health and Alcohol & Drug Services in the Australian Capital Territory (ACT) provide a range of prevention and treatment services delivered in a wide range of settings, such as inpatient, outpatient, community and justice health settings. The public specialist mental health service is staffed by psychiatrists, psychiatric registrars, nurses, and allied health professionals. In order to influence the service to become a more trauma-informed organisation, we were aware of several factors critical to the success of the project. This included the need for strong leadership from management to support the initiative, the importance of ongoing consultations with clinicians about their perspectives, and involving the extensive networks and partnerships in which the service was involved. Addressing the latter issue would help ensure the trauma-informed approach would be more deeply embedded in the larger health system that also provides mental health care to the population. Senior managers from the clinical service and researchers from the Australian National University, formed

a steering group to help support and manage the project. One of the research officers, with extensive experience in working with children and adolescents, was recruited from the clinical team to work on the project. During the ‘exploration’ stage, we reviewed the literature on implementing TIC within health services (Hodas 2006; MHCC 2010, 2013; NCTSN 2007; SAMHSA 2014). We conducted focus groups with clinical teams in order to understand their perspectives on the referral, treatment and management of clients affected by trauma as well as their training and support needs. Four focus group discussions were held with 24 clinicians, managers and clinical supervisors. The clinicians reported that, increasingly, clients and families were presenting with very complex presentations of trauma and adversity. A theme emerged from clinicians about their perceived lack of experience and confidence in dealing with families affected by complex trauma. For example, some clinicians felt under equipped to assess for trauma, or to respond to disclosures, and were sensitive about the possibility of doing further harm. Some staff felt they did not have the specialist skills or the time required to treat children with trauma histories. One of the biggest barriers for some clinicians was the view that ‘trauma’ is a specialised area and generally outside the scope of their practice. Although there was an emphasis on the use of evidence-based practice, there was less consensus about, and experience with, trauma-specific interventions. Consistent with prior research (Frueh et al. 2006), we found many clinicians had little prior training on how to address trauma or related symptoms, however, many indicated a strong interest in trauma-related interventions.

Developing and Delivering a Trauma-Informed Care Workshop

During 2013, the partners in this project prioritised the development of a more trauma-informed Child and Adolescent Mental Health Service (CAMHS), underpinned by principles of implementation science. The overall project was comprised of three distinct phases. Phase 1 consisted of an investigation into the prevalence of trauma and adversity in the CAMHS clinical population (Reay et al. 2015). In this phase, clinical staff participated in an embedded research study which required them to routinely assess clients for trauma histories. The findings revealed that 69% of children and adolescents who accessed the service had experienced a potentially traumatic event. Furthermore, children with trauma histories were more likely to have a parent with a trauma history (Reay et al. 2015). In order to support the clinical teams and address their concerns about routine screening for trauma histories in their clients, a TIC workshop was developed. Thus, Phase 2 involved the development, implementation and evaluation of TIC training for staff. Phase 3 involves the implementation and evaluation of

an evidence-based trauma-specific intervention. Informed by implementation science frameworks, we were cognisant of the many contextual factors (e.g. the setting, therapist, organisational and system factors) that would guide and influence the success of the implementation process (Aarons et al. 2011). The implementation of TIC training was further divided into four critical stages: ‘exploration’, ‘preparation’, ‘implementation’, and ‘sustainment’. This study was approved by the ACT Health Human Research Ethics Committee on 16 May 2013 (ETH. 11.12.281).

Method

Workshop Evaluation, Design and Participants

During the ‘preparation’ stage, the authors developed a single-day workshop, utilising a combination of didactic presentations and interactive approaches. The workshop content was based on recommendations in the literature on the essential components of TIC programs. The workshop included the following components:

- definitions of trauma and adversity
- the prevalence of trauma in the broader community as well as amongst mental health service users
- the impact of childhood trauma on developmental trajectories and brain development
- clinical presentations that can result from early trauma experiences
- the role of attachment theory in clinical practice
- skills for assessing and responding to disclosures of trauma
- common components of evidence-based trauma therapies
- resources and referral options for clients with trauma experiences

Throughout the workshop, attendees worked on clinical vignettes which are designed to highlight behavioural and emotional manifestations of traumatic stress and their impact on an individual’s ability to engage in and respond to standard treatments. Small groups of participants receive a brief referral and are later given further details of their client’s trauma history. The unfolding vignettes aim to encourage clinicians to view client presentations, and the responses of their care-givers, through a ‘trauma lens’. They are intended to help clinicians to see how formulation, diagnosis and treatment approaches can be influenced by the presence, or absence, of a client’s trauma history. Emphasis is given to the importance of collaboration with all those who are involved with the client and their family. The workshop was not designed to train staff on trauma-specific therapies, however, it provided an overview of the common components

of various evidence-based treatments. These components include: trauma-informed assessment, establishing safety, involvement of family/carers, attention to therapeutic relationship, education about trauma (e.g. myths, impacts), provision of coping strategies and emotion regulation skills, chronological timeline or life story, exposure and desensitisation, challenging unhelpful beliefs and assumptions, and developing a sense of self. This segment is also designed to encourage clinicians to consider which of these skills they are already equipped with and what further skills training they may need.

During the ‘implementation’ phase from July 2013–2015, four workshops were conducted involving 121 participants. Participants were invited to complete pre and post study measures and all responses were anonymous. Of the 121 participants who attended the training, 113 (93%) completed the pre-training questionnaire; however, matched pre and post data was only available for 102 (84%) participants. Table 1 details the background details of course participants. The largest group of attendees were from Mental Health Services (services for children, adolescents, adults, older persons, alcohol and drug services: 73%). The remaining participants (22%) were from other services including Women, Youth and Children, Youth Mental Health centres, Youth Justice, Paediatrics, and Catholic Care services. A small number of undergraduate university students also participated (6%). The full range of professional backgrounds were represented, with the largest group comprised of nurses (36%) followed by psychologists (28%), social workers (13%), counsellors (10%), students (6%), occupational therapists (4%), psychiatrists/psychiatric registrars (2%) and paediatricians (2%). Despite high levels of clinical experience, the majority (78%) had between 0 and 2 days of previous trauma training in the past 3 years, whilst only 8% had received intensive or extensive training (5 or more days).

Measures

To assess the impact of the workshop, we measured participant confidence, awareness and attitude towards TIC at two time points: pre-training and immediately post-training. Well designed training programs can also foster positive attitudes in clinicians and reduce perceived barriers towards working with trauma. Thus, we investigated common barriers that arose from our focus group discussion with staff and from the literature on TIC. Barriers included: the view they were not equipped to deal with trauma, specialized skills and experience are required, TIC is outside their role, and anxiety about causing further distress to clients.

A pre and post-training questionnaire was administered and included qualitative and quantitative measures that were designed to align with the key content of the training materials and training goals:

Table 1 Background details of course participants

Characteristic	N	%
Division		
Child and Adolescent Mental Health Service	43	42.2
Adult Mental Health Services	20	19.6
Alcohol and Drug Services	7	6.8
University students	6	5.9
Women Youth and Children	5	4.9
Youth Justice Service	4	3.9
Older Persons Mental Health Service	4	3.9
Youth Services/Headspace	4	3.9
Catholic Care	2	2.0
Paediatrics	2	2.0
Department of Education and Training	2	2.0
Other	3	2.9
Total	102	100
Profession		
Nurses	37	36.3
Psychologists	28	27.5
Social workers	13	12.7
Counsellors/other	10	9.8
Student/undergraduates	6	5.9
Occupational therapists	4	3.9
Psychiatrists/registrar	2	2.0
Paediatricians	2	2.0
Total	102	100
Years of service		
None/undergraduate	6	5.9
1–2 years	19	18.6
3–5 years	26	25.5
6–9 years	16	15.7
10–19 years	26	25.5
20+ years	9	8.8
Total	102	100
Trauma training in last 3 years		
No prior training	15	14.9
1–4 h	41	40.6
1–2 days	23	22.8
3–5 days	14	13.9
5+ days/intensive	7	6.9
Extensive postgraduate trauma training	1	1.0
Total	101 ^a	100

^aMissing prior training data for one participant

1. A five-item measure of self-rated confidence, awareness and attitude towards trauma-informed practice was developed by the research team. The scale measured participants' confidence in assessing and responding to trauma, knowledge and skills in working with clients, relevance of training and awareness of trauma services

using a 10-point response scale (1 = not at all, 10 = very high; see Table 2).

2. A six-item checklist of perceived barriers to working with clients affected by trauma was also developed by the research team. Respondents were asked whether they could relate to a series of statements, for example, "I'm concerned about further distressing the client", "It is really outside of my role", and "None, I'm not aware of any barriers" (see Table 3). Provision was also given for an open ended response.
3. Four items on participant demographics and characteristics.
4. Three qualitative questions were developed for the post-training questionnaire relating to:
 - most important clinical aspects of workshop
 - intended changes to clinical practice
 - participants' further training needs

A 12-month follow-up questionnaire was administered to CAMHS staff only to assess for changes in their assessment and treatment practices. The survey enquired about:

1. Self-reported frequency with which they assess for trauma using the question: "How often do you ask your clients about their possible trauma experiences?" Four possible responses included: 'Always/routinely', 'Usually', 'Sometimes', or 'Rarely/Never'.
2. The uptake and training in trauma-specific interventions using open ended questions.

Data Analysis

Descriptive statistics were used to describe the sample. We were able to match participant's pre and post-training data using five variables: participant age, gender, service information, profession and date of attendance. In order to examine changes in scores from pre-test and post-test, paired samples t-tests were employed. We compared pre-training and post-training barriers using chi-squared analysis for categorical data (e.g. type of barriers) and independent samples t-tests for numerical data (total number of barriers). Undergraduate students were excluded from the analysis of barriers due to its lack of relevance. In terms of qualitative data, key themes were identified and qualitatively analysed from the open-ended responses.

Results

Prior to each workshop, participants completed a questionnaire about their expectations of the training (N = 113). Respondents reported a high level of interest in TIC training

Table 2 Pre and post-training means of confidence, awareness and attitude towards trauma and adversity (n=99)

Items ^a	Pre-training (n=99) Means (S.D.)	Post-training (n=99) Means (S.D.)	t(df)	p
The extent that trauma and adversity is relevant to your clinical work	8.45 (1.49)	9.02 (1.39)	-2.86 (98)	.005*
Level of confidence in the assessment of trauma and adversity in your clinical practice	5.02 (1.85)	7.14 (1.4)	-12.21 (98)	.001**
Level of confidence in responding to disclosures of trauma and adversity	5.38 (1.96)	7.26 (1.53)	-9.94 (98)	.001**
Level of knowledge and skills in working with individuals affected by trauma and adversity	4.90 (1.76)	6.58 (1.51)	-9.18 (99)	.001**
Level of awareness of services and resources for trauma and adversity	4.67 (2.02)	6.49 (1.75)	-8.04 (98)	.001**

Reduced n due to missing data for three participants

** $p < .001$; * $p < .05$

^aResponse range was from 0 to 10: 0 = not at all, 10 = very high

Table 3 Comparison of perceived barriers to working with clients affected by trauma and adversity pre and post training (n=95)

	Pre-training (n=95) (%)	Post-training (n=95) (%)	p
“I don’t have the specialist skills”	61.1	42.1	.127
“I don’t feel I have enough experience”	54.7	45.3	.007*
“I’m concerned about further distressing the client”	33.7	9.5*	.003*
“I’m not equipped to deal with trauma and adversity”	27.4	9.5*	.042*
“It is really outside of my role”	3.2	3.2	.751

Six undergraduates were excluded from this analysis

* $p < .05$

as well as developing specialist skills in the treatment of complex trauma. Clinicians were most interested in gaining therapeutic skills and techniques (88%), understanding clinical presentations of trauma (80%), gaining knowledge of the impact of trauma (79%) and awareness of how to ask about and respond to trauma disclosures (70%). Other topics of interest included a desire to understand the psychophysiology of trauma (69%), knowledge of the definitions of trauma (57%) and the incidence of trauma amongst our clients (56%).

Findings from the Measure of Confidence, Awareness and Attitude Towards TIC Approaches

A comparison of pre-training and post-training means for all items on the confidence, awareness and attitude measure was conducted using paired samples t-tests (Table 2). Results showed that, at pre-training, participants rated the extent that trauma and adversity was relevant to their clinical work as high (mean score: 8.45/10), which significantly increased post-training (9.02/10, $p < .05$). There was a statistically significant increase in mean levels of: confidence in assessment of trauma and adversity ($p < .001$), confidence in responding to disclosures ($p < .001$), knowledge and skills in working with individuals affected by trauma and adversity ($p < .001$),

and greater awareness of services and resources ($p < .001$) from pre to post-training. At the conclusion of the course, participants rated the training as highly relevant and beneficial to their clinical practice (mean score: 4.5/5).

Perceived Barriers to Working with Trauma

We measured clinicians perceptions of the barriers to working with individuals affected by trauma in two ways: (1) by comparing the *total number* of barriers and (2) by comparing the *types* of perceived barriers. An open-ended question was included to seek other possible responses. The responses of 95 clinicians were included in this analysis (six undergraduate student responses were excluded; see Table 3). At the conclusion of the training, there was a statistically significant reduction in three out of five perceived barriers to working with this population. For example, there was a significant reduction in the proportion of participants who felt that they “don’t have enough experience to work with clients affected by trauma and adversity” (55 vs. 45%, $p < .05$); were “not equipped to deal with trauma and adversity” (27 vs. 10%, $p < .05$), or were “concerned about further distressing a client” (34 vs. 10% $p < .05$). However, there was no statistically significant reduction in the proportion of clinicians who felt they did not have the skills to work with clients affected by

trauma (61 vs. 42%, $p = n.s.$). Prior to the workshop, only 3% reported that TIC was outside their role and this did not significantly reduce post workshop (3%, $p = n.s.$). Furthermore, at the end of TIC training there was a statistically significant reduction in the mean number of barriers identified by participants (2 vs. 1.2, $p < .05$).

Qualitative Feedback

In the post-training questionnaire, participants were asked to list the two most important aspects of the TIC training. Response were coded and collated into broad themes. Over half of respondents (57%) listed the content regarding assessment for trauma as the most important aspect of the training. This encapsulated both the importance of screening for trauma, the skills involved in asking clients about their experiences of trauma, and responding to disclosures of traumatic events. Participants also endorsed the practical components of the training as important, i.e. the role plays, case studies and group discussion of practice (37%). Specific content, such as the presentation of the commonalities across trauma therapies (24%), and teaching on the neurobiology of trauma (21%) was also mentioned. The ways in which trauma may present in clients, and the prevalence of trauma amongst the broad and specific populations was mentioned as important by 23% of participants. Participants were also asked to detail what changes to their practice they anticipated making following attending the training ($n = 97$ responses). The five most frequently reported themes are listed in Fig. 1. More than half of participants (58%) stated that they would now include routine questions regarding a person's trauma history in their assessments. One in five participants (20%) spoke about increasing their focus on the therapeutic alliance with clients. This included working at the pace of the client, focusing on listening to the client's story, validating their experiences, and having increased empathy for their clients' experiences. Post-training,

participants were asked what, if any, further training they would like to receive. The most common request was for training in specific-trauma therapy (48%). This included an expressed interest in Trauma-Focused Cognitive Behaviour Therapy, Eye Movement Desensitisation and Reprocessing (EMDR) training. Many requested training incorporating more practical skills and role play (28%).

12-Month Follow-Up

Given that the TIC workshop was specifically developed for the needs of CAMHS clinicians, we were interested in the impact of the training on their assessment and treatment practices over time. 12 months post-training, an online survey was distributed to CAMHS clinical staff. Of the 43 CAMHS clinicians who participated in TIC training, 22 responded to the follow-up questionnaire (51%). There were no significant differences between the CAMHS responders and non-responders in terms of their professional backgrounds, years of service or previous training in trauma approaches. The majority of respondents (81%) reported they 'usually or always' screen for potentially traumatic events. Whilst we do not have historical data, this quantifies what has been qualitatively observed in the service: staff are shifting toward viewing clients and families through a trauma-informed lens. Moreover, 80% of respondents had gone on to receive training in Trauma-Focused Cognitive Behavioural Therapy (TF-CBT) and had access to follow-up individual or group supervision. Their responses to the open-ended question about their experiences with the program included: "the trauma-informed training has been excellent across the service and has improved our ability to work with clients" and "TF-CBT is well worth the investment". Another clinician with no prior experience in the TIC approach commented: "I think that the conversations we are having in the training and supervision are totally relevant... and the trauma focus should inform all our interactions with clients".

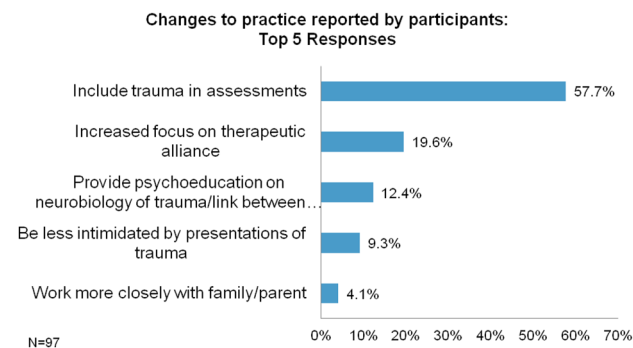


Fig. 1 Intended changes to practice following TIC training as reported in open-ended question ($n = 97$). Reduced n due to missing data for five participants

Discussion

The results from the TIC training confirm that a brief course, delivered to a broad range of health professionals is associated with an increase in their self-reported confidence, awareness and attitude towards the assessment and treatment of people exposed to trauma and adversity. In addition to a greater willingness to incorporate a trauma history into their assessments, participants indicated they had greater confidence in their ability to acknowledge and address a person's traumatic past. This is a critical change given historically mental health services' rates of screening for trauma are very low (Xiao et al. 2016). Following the training there was a

significant reduction in the common barriers to working with this population such as fears of causing further distress to clients, being poorly equipped or lacking experience. Prior to the workshop only 3% reported that TIC was outside their role although this did not significantly reduce post workshop (3%). Participants also stressed the importance of building trust, being respectful and non-judgmental, whilst supporting their client's strengths and resources. The proportion of staff who were concerned that working with such clients requires a specialised set of skills reduced from pre to post workshop (61 vs. 41%), but was not significantly different. We found evidence that the workshop stimulated interest in and readiness for advanced clinical skills and trauma-specific interventions, an important goal of TIC training (Layne et al. 2011). Within 12 months of the TIC training, the majority of CAMHS staff had been trained to deliver TF-CBT (Cohen 2006) and were receiving regular trauma-informed supervision on their cases.

The current study has several limitations that should be considered in interpreting the results. The questionnaire used was a self-appraisal instrument with no questions designed to test participants' *actual* knowledge or observed practice changes. There were some differences within the mixed sample which included community health and mental health professionals: some participants received the workshop as 'mandatory' training (CAMHS staff), whereas others 'self selected' to attend. It is possible that those who 'self select' had a bias towards a greater interest in or prior knowledge of TIC. On the other hand, although the majority of attendees were very experienced, only a small proportion had exposure to trauma related training in 3 years prior to the workshop. The study could have been strengthened by the use of psychometrically validated measures of confidence, knowledge and attitudes. However, a recent study into outcomes from trauma-training reported that such general questionnaires were not specific enough to detect change in participants and trauma-specific questionnaires are required (Beidas et al. 2016). The relatively small sample of participants in the follow-up questionnaire, exclusively from CAMHS, limits the generalisability of these findings. This study has a number of strengths which include the reasonable sample size, the high response rate to the post-training follow-up, the use of qualitative and quantitative methods and the involvement of health professionals in the design of the clinically relevant program.

An important aspect of the project is the sustainability of the TIC approach within a dynamically changing service. This training course has evolved from a one-off session planned for a specific project, to being routinely delivered to a wider audience and integrated into the professional development training calendar of the service. The workshop was initially provided by a small multidisciplinary team of professionals with expertise in trauma, delivered to a large

group of over 40 participants. Over time, we found it can be successfully delivered by one experienced professional to smaller groups of participants with similar results. Attendees come from all professions and all divisions of the service as the applicability of TIC to all staff, administrative, allied health, medical, nursing is better understood and appreciated. Ideally, TIC provides one component of a comprehensive approach to modern mental health care. This includes trauma-informed policy and practice changes as well as training and supervision in evidenced-based, trauma-specific therapies that can be implemented in busy community mental health settings. There are some positive attempts to address the need for foundational concepts of child trauma at graduate schools (e.g. intensive training with social work students, see Layne et al. 2011). However, workshops are needed that are brief, relevant, acceptable and able to be tailored to a variety of clinical settings.

Conclusion

We found that a brief workshop based on TIC principles, delivered to a broad range of health professionals from hospital and community settings, was rated as highly useful and relevant to their clinical practice. The workshop was associated with statistically significant improvements in mean scores of participants' confidence, awareness and attitude towards using TIC principles with clients with trauma histories. There was also a significant reduction in the number of perceived barriers to working within this framework by the end of the workshop. A follow-up questionnaire indicated that the majority of CAMHS staff now routinely screen their clients for trauma histories. Their feedback revealed that the program was viewed as highly valued by staff, particularly follow-up training and supervision in trauma-specific interventions. Limitations include the reliance on self-report measures, differences within samples and staff attrition at the 12 month follow-up. Future research should investigate the effectiveness and cost effectiveness of both TIC and TF-CBT delivered in community mental health settings.

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Compliance with Ethical Standards

Conflict of interest The authors have no competing interest statements to disclose.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki

declaration and its later amendments or comparable ethical standards. This study was approved by the ACT Health Human Research Ethics Committee (ETH. 11.12.281).

Informed Consent Informed consent was obtained from all individual participants included in the study.

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