Human Trafficking and Health: A Survey of Male and Female Survivors in England

Siân Oram, PhD, Melanie Abas, MD, Debra Bick, PhD, Adrian Boyle, MD, Rebecca French, PhD, Sharon Jakobowitz, PhD, Mizanur Khondoker, PhD, Nicky Stanley, MSc, Kylee Trevillion, PhD, Louise Howard, MRCPsych, and Cathy Zimmerman, PhD

Objectives. To investigate physical and mental health and experiences of violence among male and female trafficking survivors in a high-income country.

Methods. Our data were derived from a cross-sectional survey of 150 men and women in England who were in contact with posttrafficking support services. Interviews took place over 18 months, from June 2013 to December 2014.

Results. Participants had been trafficked for sexual exploitation (29%), domestic servitude (29.3%), and labor exploitation (40.4%). Sixty-six percent of women reported forced sex during trafficking, including 95% of those trafficked for sexual exploitation and 54% of those trafficked for domestic servitude. Twenty-one percent of men and 24% of women reported ongoing injuries, and 8% of men and 23% of women reported diagnosed sexually transmitted infections. Finally, 78% of women and 40% of men reported high levels of depression, anxiety, or posttraumatic stress disorder symptoms.

Conclusions. Psychological interventions to support the recovery of this highly vulnerable population are urgently needed. (*Am J Public Health.* 2016;106:1073–1078. doi: 10.2105/AJPH.2016.303095)

Human trafficking, which involves the recruitment and movement of women, men, and children across or within national borders for the purposes of sexual, labor, and other forms of exploitation, is a serious human rights violation and important public health issue.[1] Recent estimates suggest that approximately 20.9 million people are in situations of forced labor worldwide as a result of human trafficking.[2]

The abuses endured by trafficked people have prompted calls for survivors to be provided with comprehensive and culturally appropriate health care, but little is known about survivors' health needs.[3] Although a systematic review demonstrated a high prevalence of physical and psychological morbidity among survivors in contact with posttrafficking support services,[4] the review highlighted that research has focused on women who were trafficked for sexual exploitation and had recently escaped the trafficking situation. Very little is known about survivors' medium- to long-term health, the health of women trafficked for other forms of exploitation, or the health of trafficked men.

A recent Southeast Asian survey conducted with survivors who had entered support services within the preceding 2 weeks reported a high prevalence of symptoms of physical ill health and of depression, anxiety, and posttraumatic stress disorder (PTSD) among both trafficked men and women.[5] A study of female Moldovan survivors revealed that 55% met the diagnostic criteria for mental disorders, predominantly depression and PTSD, 6 months after returning home.[6] These studies suggest that psychological morbidity may be increased by violence before and during trafficking and by poor social support and unmet needs in the posttrafficking period.[5,6]

Evidence to inform policies and services in high-income country settings remains limited, as most research has been conducted in low- and middle-income countries, mainly in South and Southeast Asia and the post-Soviet states. To our knowledge, the study described here is the first to investigate the physical and mental health of male and female trafficking survivors in a high-income country.

METHODS

We derived our data from a cross-sectional survey of trafficking survivors conducted in England. Interviews took place over a period of 18 months (June 2013–December 2014).

Eligibility

Individuals were eligible for the study if they were aged 18 years or older, had experienced human trafficking, had been identified as a victim of human trafficking by statutory or voluntary agencies, and had previously received or were currently receiving assistance from one or more statutory or voluntary agencies. Human trafficking was defined in accordance with the United Nations Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Girls.[7] People were excluded if they remained in the exploitation setting, they were too unwell or distressed to participate, or they were unable to provide

ABOUT THE AUTHORS

Siân Oram, Melanie Abas, Sharon Jakobowitz, Kylee Trevillion, and Louise Howard are with Health Service and Population Research, King's College London, London, England. Debra Bick is with the Faculty of Nursing and Midwifery, King's College London. Adrian Boyle is with Addenbrookes Hospital, Cambridge, England. Rebecca French is with the Department of Social and Environmental Research, London School of Hygiene & Tropical Medicine, London. Mizanur Khondoker is with the Department of Biostatistics, King's College London. Nicky Stanley is with the School of Social Work, University of Central Lancashire, Preston, England. Cathy Zimmerman is with the Department of Global Health and Development, London School of Hygiene & Tropical Medicine.

Correspondence should be sent to Cathy Zimmerman, PhD, London School of Hygiene & Tropical Medicine, 15-17 Tavistock Pl, London WC1H 9SH, United Kingdom (e-mail: cathy.zimmerman@lshtm.ac.uk). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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TABLE 1—Characteristics of Men and Women in Contact With Posttrafficking Support Services: England, June 2013–December 2014

Characteristic	Men (n = 52), Mean ±SD, No. (%), or Median (IQR)	Women (n = 98), Mean (SD), No. (%), Median (IQR)	*P*
Pretrafficking			
Age left education, y	18.1 ±3.4	16.2 ±6.2	.02
Violence experienced before trafficking			
Physical violence	15 (28.9)	57 (58.2)	.002
Sexual violence	2 (3.9)	30 (30.6)	.001
Trafficking			
Type of exploitation			< .001
Domestic servitude	5 (9.6)	39 (39.8)	
Sexual exploitation	1 (1.9)	42 (42.9)	
Labor exploitation	45 (86.5)	14 (14.3)	
Months in trafficking situation	3 (1–5)	12 (5–60)	.01
Hours worked per d			< .001
≤ 8	4 (7.7)	9 (9.2)	
9–12	26 (50.0)	18 (18.4)	
≥ 13	13 (25.0)	24 (24.5)	
No fixed hours	5 (9.6)	30 (40.8)	
No weekly rest day	24 (46.2)	64 (65.3)	.06
Threats to self during trafficking	36 (69.2)	82 (83.7)	< .001
Threats to family during trafficking	16 (30.8)	47 (48.0)	< .001
Violence experienced during trafficking			
Physical violence	22 (42.3)	75 (76.5)	< .001
Sexual violence	2 (3.9)	65 (66.3)	< .001
Injury during trafficking	17 (32.7)	66 (67.4)	< .001
Poor living conditions during trafficking			
Locked in a room	11 (21.2)	47 (48.0)	.004
Living/sleeping in overcrowded rooms	30 (57.7)	35 (35.7)	.04
Sleeping in dangerous conditions	5 (9.6)	4 (4.1)	.37
Nowhere to sleep/sleeping on the floor	29 (55.8)	32 (32.7)	.02
Poor basic hygiene	20 (38.5)	14 (14.3)	.003
Inadequate food	35 (67.3)	39 (39.8)	.006
Inadequate drinking water	13 (25.0)	11 (11.2)	.09
No clean clothing	17 (32.7)	31 (31.6)	.92
Being made to drink alcohol	7 (13.5)	26 (26.5)	.16
Being made to take illegal drugs	5 (9.6)	14 (14.3)	.64
Being made to take medications	5 (9.6)	12 (12.4)	.81
No access to passport/identity documents	22 (42.3)	68 (69.4)	.003
Extreme restriction of movement	30 (60.0)	78 (81.3)	.005
Posttrafficking			
Age, y	36.8 (11.9)	30.0 (9.4)	.001
Currently married/living with a partner	13 (25.0)	8 (8.3)	.006
Has ≥ 1 children	29 (55.8)	52 (53.6)	.80

Continued

informed consent. No restrictions were placed on exploitation type, time since exploitation, country of origin, or language.

Recruitment

A 2-stage sampling strategy was used to recruit participants. First, the research team requested assistance from 19 voluntary-sector organizations that either provided government-funded posttrafficking support or were authorized to refer potential victims of human trafficking for such support and from 10 health care organizations and 15 social services departments located in areas in which high numbers of victims of trafficking had been previously identified. Nine voluntary organizations did not respond, and one voluntary organization and 5 social services departments declined to provide assistance.

In the second stage, participating organizations approached a convenience sample of potential participants, provided basic study information, and worked with the study team to schedule research interviews. Participating organizations were based in London and in eastern, southeastern, western, and northwestern England. Face-to-face interpretation was provided as required by qualified independent interpreters. Travel and child-care expenses were reimbursed, and participants were given a £20 ($28) shopping voucher.

Measures

Instruments that had been validated among people who experienced trauma and abuse were used in the survey. Data were collected on sociodemographic characteristics, pretrafficking and trafficking experiences, medical history and physical health, psychological health, substance use, sexual and reproductive health, and unmet social care needs.

The sociodemographic characteristics assessed included gender, age, country of origin, education, marital status, and number and location of children. Data on pretrafficking and trafficking experiences included type and duration of exploitation, time since escape, living and working conditions, and violence.[5] Extreme restriction of movement was defined as never being allowed to travel unaccompanied, being locked in a room, or both.

Questions from the 2007 English Adult Psychiatric Morbidity Survey were used to

TABLE 1—*Continued*

Characteristic	Men (n = 52), Mean ±SD, No. (%), or Median (IQR)	Women (n = 98), Mean (SD), No. (%), Median (IQR)	*P*
Months since left trafficking situation	3 (1–6)	16 (3–38)	< .001
Months of contact with support services	1.6 (0.9–4.3)	4.4 (1.4–12.5)	< .001
Still afraid of traffickers	29 (55.6)	78 (78.6)	.002
No. of unmet needs	2 (1–3)	3 (1–4)	.57
Lacks a confidante	18 (34.6)	31 (31.6)	.11

Note. IQR = interquartile range. The sample size was n = 150.

assess medical history (including psychiatric disorders).[8] Participants were categorized as having a chronic medical condition if they had been diagnosed with one or more of the following: arthritis, asthma, bronchitis, diabetes, epilepsy, hepatitis, heart disease, high or low blood pressure, HIV, kidney problems, or tuberculosis. Physical symptoms were assessed with the Miller Abuse Physical Symptoms and Injury Survey.[9] Severe symptoms were defined as symptoms that bothered the participant "quite a lot" or "extremely" (vs "not at all" or "a little").

With respect to psychological health, probable depressive disorder was assessed as a score of 10 or more on the Patient Health Questionnaire-9,[10] probable anxiety disorder as a score of 10 or more on the Generalized Anxiety Disorder 7 scale,[11] and probable PTSD as a score of 3 or more on the 4-item version of the PTSD Checklist–Civilian.[12] Participants were categorized as having high levels of psychological symptoms if they screened positive for probable depressive disorder, anxiety disorder, or PTSD. The Revised Clinical Interview Schedule[13] was used to assess suicidality; participants who endorsed 2 or more items were categorized as suicidal.

High-risk alcohol use was classified as a score of 5 or more on the Alcohol Use Disorders Identification Test–Consumption.[14,15] Drug use was assessed via questions from the British Crime Survey.[16] Questions adapted from the third UK National Survey of Sexual Attitudes and Lifestyles were used to assess sexual and reproductive health, including diagnosed sexually transmitted infections (STIs).[17]

Finally, a modified 15-item version of the Camberwell Assessment of Need Short Appraisal Schedule was used to assess unmet social care needs.[18,19] Interviewers rated items as representing "no problem," a "met need," or an "unmet need" according to participants' reports of their current situation. Higher scores reflect a greater level of unmet need.

Data Analysis

We used Stata version 11 (StataCorp LP, College Station, TX) in conducting our analyses. Descriptive statistics (percentages for categorical variables and either means and standard deviations or medians and interquartile ranges [IQRs] for continuous variables) were used to describe sociodemographic and trafficking characteristics and other variables of interest. Bivariate analyses were stratified by gender and conducted via logistic regression models.

RESULTS

Of the 169 people invited to participate in the study, 150 (88.8%) consented (98 women and 52 men). Of the 19 people who were invited but did not participate, 7 did not take part because of health reasons, including serious physical illnesses, advanced stages of pregnancy, and high levels of psychological distress. Sixty-nine (46%) interviews were conducted with the assistance of an interpreter.

Sample Characteristics

Participants originated from more than 30 countries, including Nigeria, Poland, and Albania. Women were most often trafficked for sexual exploitation or domestic servitude. More than four fifths of men were trafficked for labor exploitation, working in settings including agriculture (26.9%), construction (15.7%), and car washing (13.7%). Female participants were generally younger than male participants, had spent less time in education, and were less likely to be currently married or living with a partner but were equally likely to have children (Table 1). Forty-two percent of women who had children reported that their children lived with them. By contrast, only 3.5% of men with children reported that their children lived with them; 42% reported that their children lived with their current or former partner.

Health Risks Before and During Trafficking

Women reported that they been in the situation of exploitation for a median of 12 months (IQR = 5–60), and the median time since escape was 16 months (IQR = 3–38). By contrast, men reported having been exploited for a median of 3 months (IQR = 1–12), with a median time since escape of 3 months (IQR = 1–6). Sixty percent of men and 81.3% of women reported extreme restriction of movement during trafficking, as did 52.6%, 83.7%, and 90.7% of people trafficked for labor exploitation, domestic servitude, and sexual exploitation, respectively.

Overall, 42.3% of men and 76.5% of women reported physical violence during trafficking. Injuries were sustained by 32.7% of men and 67.4% of women as a result of either violence or occupational accidents; 21.2% of men and 23.5% of women reported that these injuries caused ongoing pain or difficulty.

Two thirds of women reported being forced to have sex during trafficking, including 95% of women trafficked for sexual exploitation, 54% trafficked for domestic servitude, and 21% trafficked for other forms of labor exploitation. Seventy-one percent of the participants reported that they remained afraid of the traffickers even after they were out of the trafficking situation.

The prevalence of pretrafficking violence was also high. In total, 28.9% of men and 58.2% of women reported pretrafficking physical violence. In addition, 30% of women reported pretrafficking sexual violence, perpetrated predominantly by partners (9.2%) and family members (5.1%).

Physical, Sexual, and Mental Health

The most commonly reported severe physical symptoms were headaches, being easily tired, back pain, dizzy spells, and

TABLE 2—Physical and Mental Health of Human Trafficking Survivors: England, June 2013–December 2014

Symptom Category	Men (n = 52), No. (%)	Women (n = 98), No. (%)	P
Constitutional symptoms			
Easily tired	9 (17.3)	55 (56.1)	< .001
Weight loss	3 (5.8)	7 (7.1)	.73
Loss of appetite	2 (3.9)	33 (33.7)	< .001
Neurological symptoms			
Headaches	11 (21.2)	57 (58.2)	< .001
Dizzy spells	7 (13.5)	31 (31.6)	.02
Memory problems	5 (9.6)	38 (38.8)	< .001
Fainting	1 (1.9)	5 (5.1)	.33
Gastrointestinal symptoms			
Stomach pain	4 (7.7)	25 (25.5)	.009
Vomiting, upset stomach, constipation or diarrhea	1 (1.9)	20 (20.4)	.002
Cardiovascular symptoms			
Chest/heart pain	5 (9.6)	20 (20.4)	.10
Breathing difficulty	3 (5.8)	17 (17.4)	.05
Musculoskeletal symptoms			
Back pain	5 (9.6)	34 (34.7)	.001
Dental pain	4 (7.8)	29 (29.6)	.002
Eye, ear, and upper respiratory symptoms			
Eye pain	5 (9.6)	10 (10.2)	.86
Ear pain	4 (7.7)	5 (5.1)	.55
Dermatological symptoms (rashes, itching, sores)	4 (7.7)	24 (24.5)	.01
Psychological symptoms			
Depression, anxiety, or PTSD	21 (40.3)	79 (77.6)	< .001
Depression	12 (23.1)	50 (51.0)	.001
Anxiety	10 (19.2)	48 (49.0)	.001
PTSD	13 (25.0)	58 (59.2)	< .001
Suicidal ideation	7 (13.5)	50 (51.0)	< .001
High-risk drinking	17 (33.3)	4 (4.1)	< .001
Drug use (in past month)	3 (5.8)	4 (4.1)	.57
Sexually transmitted infection	4 (7.7)	22 (22.5)	.04

Note. PTSD = posttraumatic stress disorder. The sample size was n = 150.

memory problems (Table 2); the prevalence of each of these symptoms was significantly higher among women than among men. Forty-five percent of participants reported chronic medical conditions. Overall, 7.7% of men and 22.5% of women reported diagnosed STIs.

The prevalence of probable depressive disorder, anxiety disorder, or PTSD (i.e., the prevalence of high levels of psychological symptoms) was 69.8%, and 38.0% of the participants reported suicidal ideation. Women were more likely than men to report high levels of psychological symptoms (odds ratio [OR] = 4.0; 95% confidence interval [CI] = 1.8, 8.6) and to report suicidal ideation (OR = 6.7; 95% CI = 2.8, 16.3). Fourteen percent of the participants reported hazardous alcohol use, with men at increased risk relative to women (OR = 11.4; 95% CI = 3.6, 36.3).

No participants reported a history of psychotic illnesses, but 10.5% had unmet treatment needs relating to hearing voices or seeing things that were not there; all but 2 of these participants met the criteria for probable PTSD. Unadjusted odds of high levels of psychological symptoms were elevated among women who reported pretrafficking physical violence, sexual violence during trafficking, and, in the posttrafficking period, ongoing fear of the traffickers and increasing numbers of unmet social needs (Table 3). Among men, unadjusted odds of high levels of psychological symptoms were elevated among those who reported ongoing fear of the traffickers and lacking a confidante in the posttrafficking period.

Unmet Social Needs

Participants had a median of 2 (IQR = 1–4) unmet social needs, with more than a quarter having unmet needs relating to budgeting and not having enough money for essential items, accessing benefits, social lives, or having enough to do. One third reported that they did not have family or friends in whom they could confide.

DISCUSSION

This study is the first to our knowledge to offer evidence on the medium- to long-term health of female and male trafficking survivors. It is also among the first studies to investigate the health of trafficking survivors in a high-income setting. Our findings indicate that many survivors experience medium- to long-term physical, sexual, and mental health problems, including injuries, STIs, and probable depression, anxiety, and PTSD.

Our results also highlight the high levels of violence experienced by trafficked people and their ongoing fear of the traffickers in the posttrafficking period; nearly three quarters of participants perceived that they were still in danger from their trafficker. Survivors will need psychological support to address the chronic and multiple traumatic events they have experienced along with careful risk assessments and safety planning, particularly if they are returning to their countries of origin. Importantly, women trafficked for domestic servitude experienced high levels of sexual violence during trafficking, and both men and women reported a high prevalence of diagnosed STIs. Comprehensive sexual health services are needed for trafficked people, regardless of the type of exploitation suffered.

Our study lacked sufficient power to detect differences in the risk of high levels of

TABLE 3—Association of Pretrafficking, Trafficking, and Posttrafficking Factors With High Levels of Psychological Symptoms: England, June 2013 to December 2014

Variable	Men			Women		
	Without Symptoms (n = 22), No. (%) or Mean ±SD	With Symptoms (n = 21), No. (%) or Mean ±SD	OR (95% CI)	Without Symptoms (n = 20), No. (%) or Mean ±SD	With Symptoms (n = 76), No. (%) or Mean ±SD	OR (95% CI)
Pretrafficking						
Pretrafficking diagnosed mental disorder	0 (0.0)	2 (9.5)	. . .	2 (10.0)	6 (7.9)	0.8 (0.1, 4.3)
Left education at < 15 y	5 (22.7)	4 (19.1)	0.75 (0.2, 3.3)	4 (20.0)	29 (38.2)	2.2 (0.7, 7.4)
Physical violence	6 (27.3)	7 (33.3)	1.3 (0.4, 4.9)	8 (40.0)	49 (67.5)	2.8 (1.0, 7.8)
Sexual violence	0 (0.0)	2 (9.5)	3.2 (0.7, 15.4)	3 (15.0)	27 (35.5)	1.1 (0.4, 3.1)
Trafficking						
Physical violence	9 (40.9)	11 (52.4)	2.17 (0.6, 7.4)	15 (75.0)	59 (77.6)	1.3 (0.4, 4.2)
Sexual violence	0 (0.0)	2 (9.5)	1.2 (0.3, 5.6)	9 (45.0)	56 (73.7)	3.1 (1.1, 8.8)
Injury during trafficking	4 (19.1)	8 (38.1)	2.6 (0.6, 10.6)	10 (58.8)	56 (77.8)	2.5 (0.8, 7.5)
Extreme restriction of movement	10 (45.5)	15 (71.4)	3.6 (1.0, 13.4)	13 (65.0)	60 (79.0)	2.3 (0.8, 6.8)
No. of poor living situations during trafficking	2.5 ±2.0	2.9 ±1.4	1.1 (0.8, 1.6)	1.6 ±1.4	1.7 ±1.3	1.1 (0.7, 1.6)
Type of exploitation						
Labor	21 (95.5)	16 (80.0)	1 (Ref)	4 (20.0)	10 (13.2)	1 (Ref)
Domestic	1 (4.6)	3 (15.0)	3.9 (0.4, 41.5)	6 (30.0)	31 (40.8)	2.1 (0.5, 8.8)
Sexual	0 (0.0)	1 (5.0)	. . .	10 (50.0)	32 (42.1)	1.3 (0.3, 5.0)
Duration of exploitation, mo[a]	3.0 ±11.1	2.9 ±5.8	0.99 (0.7, 1.3)	14.3 ±7.2	12.8 ±4.5	1.0 (0.7, 1.3)
Time since exploitation, mo[a]	3.3 ±3.8	3.4 ±3.9	1.0 (0.7, 1.6)	6.7 ±4.8	14.6 ±4.7	1.4 (1.0, 1.9)
Posttrafficking						
Age, y	36.7 ±11.5	31.3 ±9.6	0.95 (0.9, 1.0)	30.0 ±10.9	29.9 ±9.1	1.00 (0.9, 1.0)
Not married/cohabiting	17 (77.3)	15 (71.4)	1.4 (0.4, 5.4)	17 (85.0)	69 (90.8)	1.5 (0.2, 13.1)
Has children	12 (54.6)	9 (42.9)	0.6 (0.2, 2.1)	8 (40.0)	43 (56.6)	1.8 (0.7, 5.0)
≥1 diagnosed chronic health problems	9 (40.9)	9 (42.9)	1.1 (0.3, 3.6)	6 (30.0)	31 (54.0)	2.7 (0.9, 7.9)
Ongoing fear of traffickers	10 (45.4)	16 (76.9)	3.8 (1.0, 14.2)	13 (65.0)	64 (84.2)	3.5 (1.1, 10.7)
Lacks a confidante	5 (22.7)	11 (52.4)	3.7 (1.0, 13.9)	3 (15.0)	28 (36.8)	3.1 (0.8, 11.5)
Time in contact with services, mo[a]	1.6 ±3.1	2.1 ±3.5	1.2 (0.7, 2.1)	4.4 ±3.3	4.7 ±3.8	1.0 (0.7, 1.5)
No. of unmet social needs[b]	1.2 ±0.7	2.3 ±0.6	1.9 (0.9, 4.2)	0.8 ±0.7	2.6 ±0.6	2.9 (1.5, 5.4)

Note. CI = confidence interval; OR = odds ratio. The sample size was n = 150.

[a]Log transformed data.

[b]Square root transformed data.

psychological symptoms in relation to pretrafficking, trafficking, and posttrafficking factors. Our analysis suggests, however, that such risk may be heightened among survivors who have experienced violence before and during trafficking and who, once out of the trafficking situation, have ongoing fear of their traffickers and have a higher number of unmet social needs (e.g., financial difficulties and social isolation). The participants' unmet social needs suggest that many of these individuals were continuing to struggle with economic insecurity and social marginalization as they attempted to rebuild their lives.

Our findings are consistent with those of previous studies, conducted predominantly in low- and middle-income country settings and with female trafficking survivors, showing an increased risk of mental health problems among women who experienced violence prior to and during trafficking, who have poor social support, and who have higher numbers of unmet needs.[6,20] In contrast to previous research, we did not find an

association between duration of exploitation and high levels of psychological symptoms.

Strengths and Limitations

This is one of the largest studies conducted to date of the health risks and experiences of female and male trafficking survivors. We used measures of physical and mental health that have been validated in multiple languages and among people who have experienced trauma and abuse; in addition, we used standard scoring methods and cutoffs. Participation was not restricted to survivors who could speak English; independent, professionally qualified interpreters assisted with interviews as required.

However, our analysis of factors that predicted high levels of psychological symptoms was limited by the study sample size, which was dependent on the number of survivors in contact with support services during the study period. Measures of physical and mental health have not been validated for trafficked populations, and it was not possible to test the validity of the measures used here.

We were able to recruit very few participants via health care provider organizations and social services, which may limit the generalizability of our results given the likelihood that most trafficking survivors are not in contact with posttrafficking support services. If survivors in contact with such posttrafficking services have more severe experiences and higher levels of need, our findings may overestimate the health risks and consequences associated with trafficking.[4] However, the consistency of our findings with those of previous studies focusing on the mental health of trafficking survivors suggests that our results may generalize to survivors using shelter services in other settings.[6,20]

Finally, for ethical reasons, we excluded survivors who were too physically or psychologically unwell to participate. It is important to note that their exclusion from the study means that there may have been some survivors in contact with support services who had more severe health needs than those reported here.

Conclusions

The findings of this study indicate that health care—including physical, mental, and sexual health care—must be a fundamental component of posttrafficking care. Female and male survivors will benefit from timely access to physical, sexual, and mental health assessments; culturally and linguistically appropriate psychological support; and, particularly, services that address their economic, social, and legal insecurity. Clear referral pathways between posttrafficking support services and medical services must be established. Finally, our results strongly suggest the urgency of testing psychological interventions to support the recovery of this highly vulnerable population. AJPH

CONTRIBUTORS

S. Oram, M. Abas, D. Bick, A. Boyle, R. French, N. Stanley, K. Trevillion, L. Howard, and C. Zimmerman designed the study. S. Oram, S. Jakobowitz, N. Stanley, and K. Trevillion collected the data. S. Oram, S. Jakobowitz, M. Khondoker, L. Howard, and C. Zimmerman analyzed the data. S. Oram, S. Jakobowitz, L. Howard, and C. Zimmerman wrote the first drafts of the article. All of the authors critically revised the article.

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HUMAN PARTICIPANT PROTECTION

This study was approved by the National Research Ethics Service Committee South East Coast–Kent. All of the participants provided written informed consent.

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