Interventions to support reproductive and mental health amongst care leavers: a systematic review

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Abstract

Compared to other teenagers, young care leavers (CLs) tend to have poorer sexual/reproductive and mental health. Mental health difficulties may increase risk for poor sexual/reproductive health. This systematic review addresses a gap in knowledge regarding effectiveness of existing interventions that support CLs sexual/reproductive health (e.g., contraception, pregnancy choices, early parenting). Eight published articles spanning six interventions were eligible. Interventions were associated with improvements in a range of sexual/reproductive health measures (e.g., sexual health knowledge; knowledge of where to get support; attitudes to sexual health practices), with some indicative improvements in self-esteem. However, some studies suggested these improvements may not be sustained. Interventions tended to include a broad age range, with limited programmes specifically aimed at CLs. Whilst some programmes focused on attitudes toward reproductive health and pregnancy (i.e., contraception), we identified no programme focusing on parenthood choice. We also identified no sexual/reproductive health programme that targeted or assessed associated mental health problems, despite evidence of associations between sexual health and mental health difficulties. Findings suggest that CLs may benefit from specific sexual/reproductive health supports, but further evidence is needed. Findings also indicate a need for more holistic supports that integrate mental health supports with reproductive/sexual health, and consider CL decision-making.

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Introduction

Prevalence of care leavers & context

The number of children in care in England and Wales has continued to rise steadily. Recent estimates (in 2022) suggest that 82,170 children were looked after, up 2% from the previous year, with 5,570 looked after children (LAC) being unaccompanied asylum seeking children (UASC), up 34% from the previous year (Department for Education, 2022). Most are placed with foster carers until the age of 18 years. At age 18 years, youth transition from being a looked after young person to a care leaver. Transition plans should begin at age 16 years (Butterworth et al., 2017). Leaving care is considered to be a challenging period. Care leavers (CLs) are more likely to face multiple challenges, and are at increased risk for a range of multiple outcomes compared to the rest of the population including poor mental health, early pregnancy and parenthood and removal of their own children from their care (Häggman-Laitila,Salokekkilä, & Karki, 2018).

Local authorities in UK have a duty to prepare young people in their care for adult life (Wade, 2011): all care leavers should have a 'pathway plan' that, wherever possible, should be jointly prepared and agreed by the child and the authority (Stein, 2019; Children Leaving Care Act, 2000). However, a recent review suggested that many Care Leavers (CLs) describe the process of leaving care as an unprepared and unfocused process, with no opportunity for CLs to participate in the decision-making regarding their own future (Häggman-Laitila,Salokekkilä, & Karki, 2018). Furthermore, in a recent report of CLs in England, almost one quarter (23%) of CLs who responded to a survey did not feel any

involvement in plans and decisions about their care, and a further 1/3 felt only 'a little involved' (UK Government, 2022). With regards to UASC arriving in the UK, many arrive in their teens and there is, therefore limited time to undertake assessments and identify provision needs whilst considering support plans for leaving care (Barrie & Mendes, 2011; Wade, 2011). It was estimated that only 12% of UASC aged 16 years and over had a pathway plan on file (Barrie & Mendes, 2011).

Evidence suggests that CLs do not benefit from the same supports and resources as non-CL counterparts (Gullo et al. 2021), often lacking support from family members, and former carers (Häggman-Laitila,Salokekkilä, & Karki, 2018). It has also been argued unaccompanied migrant care leavers (UMCLs), may be more vulnerable at this transition period, given their status as young people in care, as adolescents, as migrants and being unaccompanied (Gullo et al. 2021). It is therefore necessary to better-understand effective interventions that may promote better, more positive outcomes in this group of young people.

Studies from the US, Australia, and Ireland highlight that LAC are at increased risk of being exposed to a range of disadvantage and risk factors associated with sexual and reproductive health (Combs et al., 2022; Hyde et al., 2016a) including substance misuse, sexual exploitation, domestic and community violence, trauma, numerous placements and unstable living situations, as well as mental health challenges (Buttram et al., 2019; Harmon-Darrow, Burruss, & Finigan-Carr, 2020; Lieberman et al., 2014). Indeed a history of previous abuse and neglect and subsequent mental health issues may lead to difficulties in navigating and negotiating sexual relationships (Purtell, Mendes & Saunders, 2020).

Sexual and reproductive health of care leavers

Compared to other teenagers, young CLs tend to have poor sexual and reproductive health (Combs et al., 2022), including poorer contraceptive use, increased rates of transmission of STIs and HIV (Nixon et al., 2019). International evidence suggests that CLs, including those in the UK, are also more likely to experience unintended early pregnancy/parenthood, are less likely to choose pregnancy termination, and, more likely to experience the removal of children from their care (Buttram et al., 2019; Chase et al., 2006; Combs, Begun et al., 2018; Combs et al., 2022; Craine et al., 2014; Häggman-Laitila,Salokekkilä, & Karki, 2018; Mezey et al., 2017; Purtell, Mendes & Saunders, 2020; Roberts et al., 2017; Vinnerljung et al., 2007; Wall-Wieler et al., 2018).

Whilst few studies consider whether pregnancies were wanted or intended (Ethier, 2022), it is important to recognise that early parenthood may be considered as a positive experience for some, and for others it may be a less positive choice (Mezey et al., 2017; Roberts et al., 2017). For example, evidence from US and UK highlights that early motherhood may be perceived as a way of rectifying earlier adverse experiences, providing stability and meeting emotional needs, a chance to be part of a family, and motivation and opportunity for achievement and responsibility (Aparicio, Pecukonis, & O'Neale, 2015; Chase et al., 2006; Knight et al., 2006; Radey et al., 2016; Mezey et al., 2017). However, one recent study of LAC from US suggested that only 10% held pro-pregnancy attitudes, with over half experiencing anti-pregnancy attitudes, and the remaining one third holding ambivalent beliefs (Combs, Brown et al., 2018). Studies from both US (Combs, Begun et al., 2018; Shpiegel & Cascardi, 2018) and UK (Chase et al., 2006; Mezey et al., 2017; Sackler 2021;) highlight that early parenthood is also associated with a range of adverse socioeconomic and health outcomes, including mental health difficulties. Despite the

challenging decisions associated with early parenthood, one study suggested that less than 50% of care experienced youth who faced parenthood said they had received support to help make a decision about a pregnancy, and most reported pressure from professionals, carers, or birth parents to have an abortion (Chase et al., 2006). Whilst there is limited evidence regarding parenthood choice, more recent studies suggest that LAC and care leavers receive little support and advice to support contraception and contraception choice (Hyde et al., 2016a; Dworsky & Courtney, 2010).

This evidence highlights the need to better understand supports for CLs regarding contraception, pregnancy, and parenting choice. The focus of the current review is on interventions that focus these specific indicators of sexual/reproductive health.

Care Leaver's mental health

Young people in the UK who are LAC (Rees, 2013) and CLs (Stein & Dumaret, 2011) demonstrate the highest rates of mental ill health, but the poorest access to mental health services (Butterworth et al., 2007), with rates of mental illness up to six times greater compared to non-care experienced peers (Butterworth et al., 2017). Care-leavers are more likely to self-harm, commit suicide, exhibit risk-taking behaviours and have higher rates of psychopathology compared to non-care experienced peers (Butterworth et al., 2017; Häggman-Laitila,Salokekkilä, & Karki, 2018; Harder et al., 2020). For example, it has been estimated that, in UK, 57% of young people living in foster care and 96% of those in residential care had some form of psychiatric disorder, compared to 15% of those living with their families (Stein & Dumaret, 2011). An early English study found that almost two thirds of CLs had thought about taking their own lives, with 40% having tried to at the time they were leaving care (Saunders & Broad, 1997 in Stein & Dumaret, 2011). Another UK studies

examining mental health of CLs as they transitioned out of care (Dixon et al., 2006; 1997 in Stein & Dumaret, 2011) found that at baseline (approaching transition out of care), around 42% experienced emotional and behavioural difficulties. This study also provided evidence of an increase in mental health problems across the transition out of care: 12 to 15 months later, the proportion of CLs reporting mental health problems doubled (from 12% to 24%), and 4% had made suicide attempts. Further research also suggests increases in mental health problems after leaving care, with a study in Scotland suggesting a fourfold increase in youth mental health problems after leaving care (Dixon & Stein, 2005, in Stein & Dumaret, 2011). Furthermore, disadvantage appears to continue into adulthood, with evidence from a UK cohort study suggesting that 24% of those in care had depression by age 30 years compared to 12% of those not in care (Cameron et al., 2018).

UASC are also at increased risk of mental health difficulties, with the prevalence of psychological distress estimated to be approximately 40%-50% in UK (Ehntholt et al., 2018; Groark et al., 2011; Wade, 2011). UASC experience a range of trauma prior to arrival in the UK (Groark et al., 2011; Ehntholt et al., 2018; Sirriyeh & Raghallaigh, 2018) or other host country (e.g., Australia: Barrie & Mendes, 2011; Ireland: Sirriyeh & Raghallaigh, 2018), and continue to experience high levels of stress, and post-traumatic stress symptoms. Despite high level of mental health difficulties, a UK study suggests that only a small proportion were in contact with mental health services (Sanchez-Cao et al., 2013).

CLs may be reluctant to access mental health supports (Häggman-Laitila,Salokekkilä, & Karki, 2018). A UK study suggests that the process of leaving care can also exacerbate existing mental health difficulties (Butterworth et al., 2017), and this may be compounded by the fact that those receiving support from child and adolescent mental health services may also additionally experience a transition to adult services whilst transitioning out of

care (Butterworth et al., 2017; Häggman-Laitila,Salokekkilä, & Karki, 2018). This points to substantial and persistent unmet mental health needs of care experienced youth, and a need to improve access to a range of services (Bunger et al., 2021; Harder et al., 2020).

Links between reproductive health and mental health

There is a robust association between poor mental health and poor sexual/reproductive health behaviour (Patel et al., 2007): mental health problems (e.g., anxiety, depression, anxiety, and self-harm) are associated with unprotected sex and STIs in adolescents (Adan Sanchez et al., 2019; Bennett & Bauman, 2000; Gambadauro et al., 2018; Harmanci et al., 2023; Hipwell et al., 2011; Ramrakha et al., 2000) and pregnancy/early parenthood (Gambadauro et al., 2018). Where research has focused on LAC and CLs, evidence from US and Australia again suggests a robust association between mental health difficulties and behaviours that increase risk for poorer sexual health outcome and early pregnancy (Lieberman et al., 2014; Buttram et al., 2019; Combs et al., 2022; Stevens et al., 2011; Purtell, Mendes & Saunders, 2020).

Considering the mechanisms through which mental health difficulties may impact on sexual and reproductive health can help to explain individual variation in risk, and thus provide insights into intervention and prevention targets. Evidence suggests that internalising problems may increase risk, at least in part, though low perceived self-efficacy/self-esteem, decreased assertiveness, and reduced ability to negotiate safe sex (Aparicio et al., 2021; Patel et al., 2007). Mental health difficulties such as anxiety and depression may also influence sexual/reproductive health via substance use, which can lower inhibitions and impair decision making (Aparicio et al., 2021; Harmanci et al., 2023; Ramrakha et al., 2000; Bennett & Bauman, 2000). Finally, LAC may not be aware of the

relationship between past trauma, mental health and sexual/reproductive health (Aparicio et al., 2021). Pre-care experiences and earlier experiences of trauma (e.g., abuse and neglect) increases risk for mental health difficulties, and may lead to difficulties negotiating sexual relationships (Nixon et al., 2019; Purtell, Mendes, & Saunders, 2020; Stevens et al., 2011). CLs may conflate sex with love and affection (Purtell, Mendes, & Saunders, 2020). LAC may also engage in behaviours associated with poorer sexual health outcomes as maladaptive coping strategies (e.g., to 'numb emotions' or feel social connections: Aparicio et al., 2021). It has also been suggested that with an accelerated transition to adulthood (compared to non-CLs), CLs may seek a partner and opt to have children (Purtell, Mendes, & Saunders, 2020).

It is important to recognise that the converse may be observed, with sexual/reproductive health predicting subsequent mental health difficulties. For example, lack of condom use has been associated with increased anxiety symptoms; and number of sexual partners has been associated with elevated depression symptoms and substance use in a study of African-American out-of-school youth (Turner et al., 2011). Other US studies suggest that if peers are aware of LAC/CLs contracting an STI, individuals may be teased or ostracised by peers, with social isolation and rejection increasing risk for subsequent mental health problems (Aparicio et al., 2021). Early pregnancy and parenthood can also have considerable impacts on youth mental health (Craine et al., 2014). Evidence suggests that where UK CLs enter parenthood, they are more likely than their non-CL counterparts to experience mental health problems (Mendes, 2009a; Roberts et al., 2017). Existing mental health problems can also make discussions regarding sexual/reproductive health more difficult for care experienced young people (Albertson et al., 2018).

These findings highlight a complex bidirectional relationship between youth mental health and sexual health (Harmanci et al., 2023), demonstrating why a more holistic approach to care may be beneficial – supporting mental health may reduce risk behaviours and support engagement with services; supporting reproductive/sexual health may reduce risk of subsequent mental health difficulties. This suggest a need to align mental health and sexual/reproductive health supports for adolescents, and particularly CLs who are considered to be at greater risk. To-date, evidence suggests that that this may be insufficiently addressed, in part due to discomfort of staff, foster carers and youth to discuss such topics (Aparicio et al, 2021). Discomfort may be linked to lack of trust, with LAC and CLs anticipating judgement and rejection, and carers and staff concerns regarding approaching such topics in a trauma-informed and sensitive way (Aparicio et al, 2021).

Interventions & supports for sexual/reproductive health & associated mental health

It is recognised that there is a disparity between the support needs and provision of care-experienced parents, with limited evidence regarding effective interventions for this population, including in the UK (Roberts et al., 2017). Whilst LAC tend to engage in early sexual activity, and may therefore require support earlier in development, evidence also suggests that supports are needed during the transition to CL (Purtell, Mendes & Saunders, 2020). Teenage Pregnancy Strategy interventions in the UK do not impact CL populations despite being highly successful in reducing teenage pregnancy incidence in the general population (Mezey et al. 2017), highlighting the need for targeted approaches. Yet there is currently a lack of evidence-based CL interventions to support contraception, pregnancy and parenthood, and associated mental health difficulties.

The aim of the present study was therefore to systematically review empirical evidence of existing interventions that support CLs regarding sexual and reproductive health

(e.g., contraception and pregnancy choices) and associated mental health, and to consider the effectiveness of such interventions. Care leaver mental health will be considered as an outcome (where assessed) in the context of reproductive health interventions, given the associations with reproductive health, and evidence that care experienced youth are at increased risk of mental health difficulties. Where possible we will examine any supports for Unaccompanied Asylum Seeking Care Leavers (UASCL) given the increased risk of adverse outcomes during this transition period for this group.

Methods

This systematic review (study protocol registered ON PROSPERO 2022 CRD42022328405) was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2015).

Sources of Information and search strategy

An electronic search was conducted through five e-databases: PubMed, Applied Social Sciences Index & Abstracts (ASSIA), Web of Science (WoS), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Social Care Online (SCIE). The search strategy consisted of three key concepts: (1) Intervention, (2) Population, (3) Reproductive Health and Parenthood. The search was limited to English language articles published from January 1st, 2002 to January 1st, 2023. Supplementary Table S1 demonstrates the building of the search query in Web of Science with keywords and synonyms. A similar approach was used for the other database. In addition, we searched references from the included studies.

Eligibility and selection criteria

Inclusion criteria for the systematic review were a) papers published in the English language; b) publication within the last 20 years; c) qualitative, quantitative and mixed methods papers; d) papers reporting on studies undertaken in the last 20 years; e) papers reporting on care leaver or/and foster care populations; f) included participants 14-25-year-olds; g) papers focusing on contraception, pregnancy or/and parenting; h) existing interventions that support care leavers/foster care youth regarding contraception, pregnancy choices and early parenting.

LBJ and RS screened articles for title and abstract independently. Independent full-text screening was then conducted. At each stage any discrepancies were discussed until consensus was reached. Both authors remained blinded during the process (see figure 1 for PRISMA diagram).

Data extraction

We extracted core information pertaining to existing effective interventions that support CLs regarding contraception, pregnancy choices, early parenting and associated mental health difficulties. We included studies that focused on sexual health knowledge, attitudes and/or behaviours in care experienced youth. We considered the study design, methodology, and intervention details. We also included country of intervention study given the different service contexts across countries. Where available we extracted information pertaining to associated mental health (intervention component and outcomes). Where available we also sought to include interventions specific to, or studies that included Unaccompanied Asylum Seeking Care Leavers (UASCLs). Feasibility and pilot studies were also included. Where reported we also included effect sizes (see Table 1).

Quality Assessment

To assess quality of each study, we used the Quality Index (QI: Downs & Black, 1998). The QI is a 27-item checklist designed for use with both randomized controlled trials and non-randomized studies. Each item is rated as 'yes' (1), 'no' (0), or 'unable to determine' (0). The QI contains four subscales: Reporting; external validity; internal validity (confounding and selection bias); and power. Items within each subscale are summed with higher scores indicating higher quality. The subscales can also be summed to give an indication of overall quality.

Results

A systematic search of five electronic databases: PubMed (*n* = 57), ASSIA (*n* = 123), Web of Science (*n* = 87), CINAHL (*n* = 223), and Social Care Online (*n* = 594), resulted in one thousand and eighty-four articles. After excluding one hundred and eighty-five articles which were duplicates or wrong publication type, eight hundred and ninety-nine were eligible for review. Eight hundred and eighty-two articles were removed at the title and abstract stage, leaving seventeen articles for full text review. Following full text screening, four papers were eligible to be included. We then reviewed references of eligible studies. We identified eight studies spanning six interventions (see Figure 1).

The six interventions were: (i)Heart to Heart Training, (ii) Smart teens Informing, Healing, Living, Empowering for Youth in or at-risk for foster care (SiHLE-YFC), (iii) Power Through Choices (PCT, (iv) Making Proud Choices (MPC) (v) Be Proud! Be Responsible!, and (vi) a peer mentoring programme (See Table 1 for a summary of studies*).* Three of the eight papers examined 'Power Through Choices', all from the same study (PCT; Green et al., 2017; Oman et al., 2016, 2018). Two papers examined *'*Making Proud Choices' (Combs et al., 2019;

Taylor et al., 2020), one of which involved an adaptation Youth in Out-of-Home Care (MPCOOH: Taylor et al., 2020). The second study allowed providers to select either 'Making Proud Choices' or 'Be Proud! Be Responsible!' (with 'Making Proud Choices being an extension of the ''Be Proud! Be Responsible!' intervention) depending on the perceived needs of their specific population (Combs et al., 2019).

All studies were conducted in the US, with the exception of one UK study (Mezey et al., 2015). All programmes targeted care experienced youth/LAC with the exception of 'Heart to Heart' training, which targeted Foster Carers (Ahrens et al., 2021). Power through Choice (Oman et al, 2016, 2018; Green 2017) targeted those in residential care which included those in care system/child welfare (i.e., foster care) in addition to those in the juvenile justice system. We identified no interventions that reported inclusions of UASCLs, nor did we identify any interventions specifically targeting this group.

Two studies recruited approximately 50/50 male-female care experienced youth (Ahrens et al., 2021; Boustani et al., 2017), although one of these studies (Ahrens et al., 2021) targeted foster carers, and 95% of their sample of caregivers was female. Three papers (Oman et al., 2017, 2018; Green et al., 2017), all from the same study and same intervention (Power through Choices) recruited 78% males, likely due to the fact that most of the residential homes in the study were male-only homes. Conversely, one study (MPCOOH; Taylor et al., 2020) recruited 70% female care experienced youth, and another study (Peer mentoring, Mezey et al., 2015) recruited 100% women. Most studies included a broad age range, from 13 to 19 years (Ahrens et al., 2021; Boustani et al., 2017; Combs et al., 2019; Oman et al., 2016, 2018; Green et al., 2017; Mezey et al., 2015), including those in care as well as those approaching the transition to CL. One study also included CLs between

ages 19 to 25 years as mentors in a peer mentoring programme (Mezey al., 2015). One study specifically focused on the period leaving care (age 18 to 23 years: Taylor et al., 2020).

With the exception of peer mentoring intervention (Mezey et al., 2015), the remaining interventions were education/curriculum based. Most interventions were six-to-eight hours in total (Heart to Heart, Ahrens et al., 2021; *Be Proud! Be Responsible!,* Combs et al., 2019; Making proud choices, Taylor et al, 2020, Combs et al., 2019; SiHLE-YFC Boustani et al., 2017), although delivery of session times varied. For example, Heart to Heart (Ahrens et al, 2021) delivered the six-hour content in one day or two half-day sessions, whereas SiHLE-YFC (Boustani et al., 2017) delivered content in four 90-minute sessions. See Table 1 for further details.

Assessment of Study Quality & Risk of Bias

We assessed four aspects of study quality (Reporting; external validity; internal validity (confounding and selection bias); and power) using the Quality Index (QI; Downs & Black, 1998). Scoring of each study using the QI can be found in Supplementary Table S2. We found that identified studies had clearly described studies, and therefore scored well on study reporting. External validity may be less robust across all studies. Studies did not report on the representativeness of the sample compared to the population they were recruiting from, and few studies reported on whether those who participated were representative of the population from which that had been recruited. Participants were not able to be blinded to the intervention they received and, as all studies relied on self-report measures, it was also not possible to blind those measuring the intervention outcomes.

Internal validity varied between studies. Five studies were randomised control trials (RCTs: Heart to Heart, Ahren et al 2021; Power Through Choices, Green et al., 2017, Oman

et al., 2016, 2018; Peer mentoring, Mezey al., 2015). Of these, two studies first include a feasibility/pilot studies as an initial phase (Heart to Heart, Ahren et al 2021; Peer mentoring Mezey al., 2015). The remaining three studies used pre-post assessments (*Making Proud Choices!/ Be Proud! Be Responsible!*, Combs et al., 2019; SiHLEYFC, Boustani et al., *2017*; MPCOOH, Taylor et al., 2020), one of which was a feasibility study (MPCOOH, Taylor et al., 2020). All studies took a longitudinal approach, but follow-up periods varied from one month (Boustani et al., 2017) to 12 months (Green et al., 2017; Oman et al., 2016, 2018; Mezey et al., 2015).

Finally, sample sizes also varied across studies. With the exception of three studies (all 'Power Through Choices' intervention: Oman et al, 2016, 2018; Green 2017) which had a sample of over 1,000 and demonstrated sufficient power to detect effects, most studies had small sample sizes with limited power. Whilst one study reported a sample size of just over 800, 72 of the participants were from foster care, with the remaining being recruited specifically from juvenile justice system (Combs et al., 2019: *Making Proud Choices! & Be Proud! Be Responsible!*). Furthermore, a number of studies identified challenges in recruitment, and/or retention at follow-up (e.g., Mezey et al., 2015; Boustani et al., 2017).

Intervention effects

It should be noted that one study (Peer mentoring, Mezey et al., 2015), as a pilot study did not aim to detect statistical intervention effects, but findings presented were indicative of possible intervention effects.

Five of the six interventions demonstrated significant improvements in sexual health knowledge (Heart to Heart, Ahrens et al., 2021; SiHLE-YFC, Boustani et al., 2017; Power Through Choice , Oman et al., 2016, Green et al., 2017; MPCOOH, Taylor, et al., 2020; *MPC*

and Be Proud! Be Responsible! Combs et al., 2019), with the peer mentoring programme not specifically assessing sexual health knowledge (Mezey et al., 2015). Three studies evaluating two interventions examined youth knowledge of where to get supports/birth control, with interventions suggesting positive impacts (Power through choice, Oman et al., 2016, Green et al., 2017, MPCOOH, Taylor, et al., 2020).

Four interventions also demonstrated improvements in attitudes to sexual health practices such as condom use (SiHLE-YFC, Boustani et al., 2017; Power Through Choice, Oman et al., 2016; MPCOOH, Taylor, et al., 2020). One of these studies found that intervention effects may impact on specific attitudes, with limited impacts on attitudes to teenage pregnancy and parenting (SiHLE-YFC, Boustani et al., 2017). Two studies also suggested that attitudes to sexual health (e.g., about STIs and pregnancy) had diminished by follow-up (SiHLE-YFC, Boustani et al., 2017; MPCOOH, Taylor, et al., 2020). Another study suggested that whilst attitudes towards condom use and birth control did improve from pre- to post-test among youth, these effects were only observed in youth in juvenile justice settings but not foster care settings (MPC and Be Proud! Be Responsible! Combs et al., 2019).

One intervention observed significant decreases in sexually risky behaviours (e.g., condom use, reported STIs and number of sexual partners: SiHLE-YFC, Boustani et al., 2017). Another intervention (Power through choice) also suggested significant effects on behavioural intentions to use condoms and birth control (Power through choice , Oman et al., 2016, Green et al., 2017), although effects were not sustained at 12-months (Oman et al., 2018). The Power through Choice intervention also demonstrated lower odds of being pregnant or getting someone pregnant compared to control group (Power through choice,

Oman et al., 2016, 2018). Similarly, a second intervention (Peer mentoring) observed that no participants became pregnant in the year between baseline and the one-year follow-up, indicative of intervention effects (Mezey et al., 2015).

Two intervention studies demonstrated increases in self-esteem (Power through choice , Oman et al., 2016, Green et al., 2017; MPCOOH, Taylor, et al., 2020), although again, effects may not be sustained with non-significant effects at follow-up (MPCOOH, Taylor, et al., 2020). A third intervention suggested data indicative of improved self-esteem (peer monitoring, Mezey et al., 2015).

Discussion

Overall this study aimed to systematically examine empirical evidence of existing interventions that support CLs regarding reproductive health (e.g., contraception, pregnancy/early parenthood choices) and associated mental health. Given that the transition out of care can begin earlier in development, we included youth from age 14 years. However, we identified few studies that focused on the transition out of care to support sexual and mental health. Indeed only one study specifically focused on youth age 18 to 23 years, aligned with transitioning out of care (Taylor et al., 2020), despite recommendations that a greater focus on support for transition out of care should be prioritised (Mezey et al., 2015).

We also aimed to examine whether these interventions included components addressing associated mental health difficulties. Indeed, recent research on CL wellbeing during lockdown suggests some of these problems have been exacerbated by the pandemic (Dadswell & O'Brien, 2022; Kelly et al., 2021), and that professionals providing help to care leavers would like interventions that can be implemented to support care leavers manage

contraception, pregnancy and early parenthood and associated mental health issues. Whilst several reviews have considered specific interventions to support mental health (Hambrick et al., 2016) and resilience (Leve et al., 2012) in LAC, there is a paucity of evidence specific to interventions and supports for CLs mental health support needs (Häggman-Laitila et al., 2020). Indeed, none of the interventions identified included mental health components or assessed associated mental health difficulties. It was therefore not possible to examine the impacts of interventions on mental health, despite evidenced associations between mental health and sexual health in CLs (Lieberman et al., 2014; Buttram et al., 2019; Combs et al., 2022; Purtell, Mendes & Saunders, 2020). A recent review of interventions for CLs in Australia suggested limited improvements in mental health post-care (O'Donnell et al., 2020). Interventions and supports for care leavers making the transition to adulthood (focusing on education, employment, housing) suggest weak evidence of the effectiveness of programmes (Häggman-Laitila, Salokekkilä, Karki, 2020; O'Donnell et al., 2020) and have limited focus on sexual and reproductive health and associated mental health problems.

Sexual health education, services and interventions are typically delivered through parents, schools, or community organisations (Combs et al., 2022; Mezey et al., 2017), but accessing these systems may be more challenging for LAC who experience disruptions in their placements, family relationships, education and schools, and such supports may therefore not reach LAC or CLs (Combs et al., 2022; Nixon et al., 2019; Purtell, Mendes & Saunders, 2020). Care experienced youth report receiving limited education or information of birth control, with less than half knowing how to access services if required (Buttram et al., 2019; Chase et al., 2006; Combs et al., 2022; Nixon et al., 2019; Stacey, 2015). Care experienced youth may lack resources to discuss sensitive topics confidentially (Combs et al., 2022; Geiger & Schelbe, 2014; Harmon-Darrow, Burruss, & Finigan-Carr, 2020).

Furthermore, care experienced youth have greater health needs but tend to have greater barriers to accessing medical care and health care information and therefore have less information regarding sexual and reproductive health (Combs et al., 2022). In addition, one study suggested that it was standard practice to share sensitive information about a LAC's sexual health across a team, which was considered to be an invasion of privacy (Hyde et al., 2016b) and may exacerbate barriers to accessing sexual and reproductive health care. The interventions identified in this review may help support care experienced youth by bridging some of these barriers to sexual health services and education.

Foster carers are an under-utilised resource (Albertson et al., 2018). In the current review, we identified only one study targeting foster carers (Heart to Heart, Ahrens et al., 2021), which suggested improvements in sexual health knowledge (in Foster carer), and improvements in carer-youth conflict and communication (Ahrens et al., 2021), although the study did not examine whether the intervention impacted on LAC sexual and reproductive health attitudes or behaviours, existing evidence suggests that that communication between parents and children about sexual relationships can have positive impacts on youth (e.g., delaying sexual activity and consistently using contraception; Mezey et al, 2017; Nixon et al., 2019; Widman et al., 2016). However foster carers may experience barriers to promoting sexual/reproductive health in LAC: they can be uncertain about their role, or feel uncomfortable providing sex and relationship information, or lack knowledge or training (Aparicio et al, 2021; Harmon-Darrow, Burruss, & Finigan-Carr, 2020; Mezey et al, 2017; Nixon et al., 2019). Sexual health training for foster carers can reduce these barriers and reduce unwanted pregnancies and STIs in youth (Albertson et al., 2018; Ahrens 2021; Nixon et al., 2019).

Whilst CLs may have difficulties in establishing and maintaining social networks (Purtell, Mendes & Saunders, 2020; Sulimani-Aidan, 2018), limited evidence suggests that peer mentoring and social support may help care leavers with a range of difficulties (Melkman & Benbenishty, 2018; Purtell, Mendes & Saunders, 2020; Økland, I., & Oterholm, 2022; Sulimani-Aidan, 2018), including addressing some of the risk factors that LAC experience for teenage pregnancy (Mezey et al., 2017), but few studies have examined the role of social support interventions for care leavers (Økland, I., & Oterholm, 2022). Furthermore, it has been suggested that mentoring may be most effective when combined with other programmes (e.g., minimum standard of income, housing, health care, education, employment or training), and more research is needed (Mendes, 2009b; Økland, I., & Oterholm, 2022). Thus, although not specific to sexual/reproductive health supports, other supports have demonstrated impacts on some aspects of sexual/reproductive health. For example, it has been suggested that supportive housing could reduce STIs among care leavers (Häggman-Laitila, Salokekkilä & Karki, 2020). Results from Multidimensional Treatment Foster Care for adolescence (MTFC-A) trials in the US indicate effectiveness in reducing pregnancy rates in girls (Leve et al., 2012). MTFC-A is a multi-component intensive foster care training programme to provide positive adult support and mentoring, close supervision, and consistent limit setting for foster care youth. This suggests that a range of supports may be beneficial for care experienced youth, and that holistic approaches targeting multiple risk factors could be beneficial.

Overall, interventions focused on sexual/reproductive health and provided evidence of intervention effects on improved knowledge of sexual health and where to get supports. Some interventions demonstrated improved attitudes to sexual health practices, although attitudes were not necessarily sustained at follow-up. Some suggested decrease in

behaviours associated with poorer sexual health outcomes (e.g., reported condom use, reported STIs and number of sexual partners), and reductions in pregnancy. These studies suggest positive impacts of interventions on measures of sexual health in LAC. In line with previous studies, findings here highlight that professionals consider and distinguish between attitudes/intentions and behaviours – for example it should not be assumed that young people who use contraception inconsistently have a desire to be pregnant (Combs, Brown et al., 2018). Indeed, in a recent study, not relying on retrospective reports, found that only 10% of foster care experienced youth held pro-pregnancy attitudes, with over half holding anti-pregnancy attitudes, and one third holding ambivalent views. Whilst some care experienced youth may view pregnancy positively, this does not necessarily indicate an intension or plan for pregnancy (Combs, Brown et al., 2018). This suggests that there is a need to better understand youth attitudes and views to better meet their specific needs and challenges (including lack of information and resource), and better support care experienced youth.

Supporting mental health in the context of sexual/reproductive health supports

Whilst the association between mental health and sexual/reproductive health is increasingly recognised both in the general population (Adan Sanchez et al., 2019; Bennett & Bauman, 2000; Gambadauro et al., 2018; Harmanci et al., 2023; Hipwell et al., 2011; Patel et al., 2007; Ramrakha et al., 2000) and LAC and CL groups (Lieberman et al., 2014; Buttram et al., 2019; Combs et al., 2022; Purtell, Mendes & Saunders, 2020; Stevens et al., 2011), understanding the mechanisms linked to the complex bidirectional processes is limited in UK and Irish context (Harmanci et al., 2023). As noted above, we identified no interventions that included mental health components or assessed associated mental health difficulties,

despite evidenced associations between mental health and sexual health. There is a need to support CLs mental health, for example regular 'mental health MOTs' for CLs throughout their adult life would ensure CLs receive appropriate support (Sackler, 2021). There is also a need to integrate mental health with existing youth programmes, including sexual/reproductive health interventions. Given the potential complex bidirectional processes (Harmanci et al., 2023), supporting mental health may reduce risk behaviours and support engagement with services; conversely, supporting reproductive/sexual health may reduce risk of subsequent mental health difficulties. Aligning mental health and sexual/reproductive health supports would lead to a more holistic approach to supporting CLs (Häggman-Laitila, Salokekkilä & Karki, 2020; Patel et al., 2007; Purtell & Mendes, 2016). Such holistic programmes should be based on the needs of care experienced youth, and should consider care-leaver decision-making (Häggman-Laitila, Salokekkilä & Karki, 2020).

Providing a range of youth health and welfare programmes and services may be less stigmatising and more accessible to youth (Patel et al., 2007). For example, 'Stand by Me' (SBM, Purtell & Mendes, 2016) was developed as an holistic support for young CLs in Australia, and was developed as an adaptation of the Personal Advisor (PA) model in the UK, to avoid siloed services and reduce gaps in support. More research is needed in this area to develop holistic models to support mental and sexual/reproductive health.

Limitations

It is important to acknowledge several potential limitations of the review of interventions. First, we identified relatively few studies addressing sexual/reproductive health in LAC or CLs. Furthermore, no studies included assessments of mental health and therefore it was not possible to examine impacts of interventions on associated mental health. It was also

not possible to conduct some planned subgroup comparisons (e.g., by gender), as most studies did not examine whether intervention effects may differ by youth gender. We also could not examine any differences by age or transition (to CL status) as most studies included a wide age range which encompassed care and the approach to the transition to leaving care but did not examine whether effects differed during this transition period. Only one study (Making Proud Choices! (MPC) For Youth in Out-of-Home Care (MPCOOH), Taylor et al., 2020) specifically considered youth as they exited care (age 18-23 years). We were also unable to examine whether effects differed by migrant status as no interventions specifically included UASCLs, nor did we identify any interventions specifically targeting this group.

Different search terms may have led to different studies being identified. In addition, the review focused on peer-reviewed published literature and there is a possibility of publication bias in locating programme evidence (studies reporting significant effects are more likely to be accepted for publication than those reporting non-significant or weaker effects). However, a number of the identified interventions did involve randomisation to treatment and control group, providing support for the relevance of sexual health supports for care experienced youth. In addition, different programmes had different follow-up periods and different levels of intensity, making it difficult to directly compare findings. It is also important to consider that some programmes included different populations or targets for intervention (foster carer; care experienced youth, those in residential care including those in juvenile justice system), and different populations may have different needs.

Notwithstanding these limitations, our review of programmes designed to support sexual health of care experienced youth suggest such programmes may reduce behaviours associated with poor sexual health outcomes and improve knowledge and attitudes

regarding reproductive health (e.g., condom use). However, further work is needed to examine support needs that recognises and supports CL decision making, including parenting choice.

Conclusions

Overall, research findings of available intervention evidence recognise the importance of supporting sexual health for care experienced youth, however, whilst several recognised the importance of focusing on attitudes to parenthood, none focused on parenthood choice. Furthermore none presently incorporate mental health needs despite associations between mental and sexual health. Furthermore, few focused specifically on supports specifically during a key transition (exiting the care system), despite evidence of increased risk during this period. This review suggests the benefit of specific supports, but further evidence is needed to better address the needs of care experienced youth.

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Tables & Figures

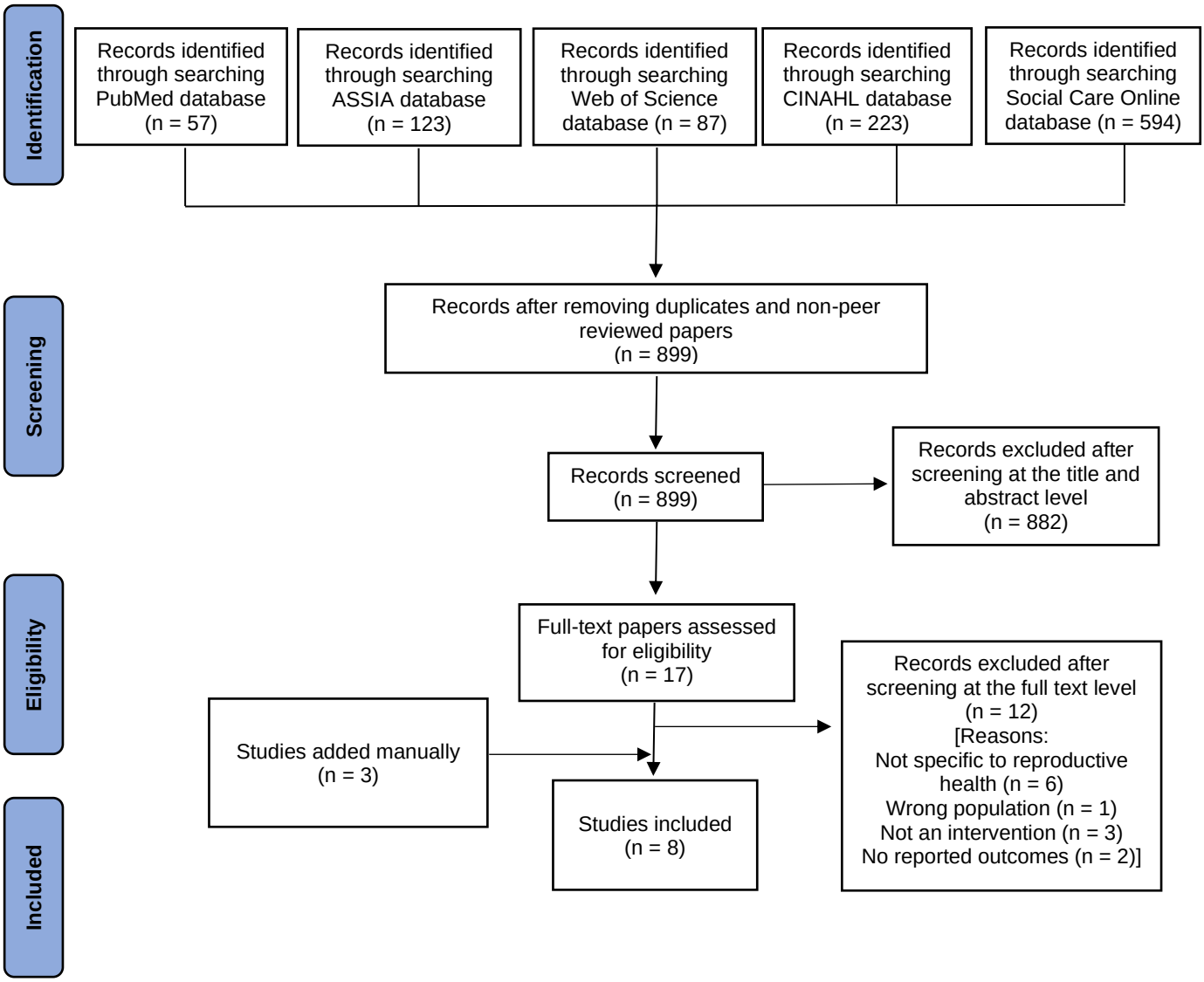

Figure 1. Prisma Diagram

Table 1: summary of interventions identified in systematic review

	Intervention name	Study	Study design	Intervention	Sample population	Measures	Outcomes	country
1	Heart to Heart training	Ahrens et al., 2021	Phase 1: feasibility study; Phase 2:longitudinal RCT with intervention & control group assessed at 1, 3, & 6 months	Heart to Heart training for foster/kinship caregivers caring for youth aged 11-21yrs 6hrs content (delivered in 1 day or 2 half days). Caregivers receive manual as personal resource which includes exercises. Also receive link to 2 brief videos (10-20mins) to reinforce skills. Videos can be watched with youth to teach skills to navigate sexual health situations & engage in effective communication when setting boundaries with partners.	Phase 1: 49 Foster/kinship carers (FKC) Phase 2: 71 participants. intervention group sizes ranged from 4 to 29 Foster youth mean age 14yrs, 52% female. (95% of care giver sample female)	*Phase 1:* • feasibility & acceptability. *Phase 2*: • caregiver communication, monitoring, & conflict behaviour • psychological behaviours	• Pilot study suggested intervention was feasible & acceptable • RCT findings: Significant improvements in intervention group compared to baseline in knowledge (p<.001), communication expectations (p<.05), & caregiver-youth conflict behaviours (p<.05) at 6months. The control group demonstrated no significant improvements. • Significant differences between groups in knowledge p<.001, communication frequency (p<.05), & conflict behaviours()p=.05) at 6 months.	US
2	Smart teens Informing, Healing, Living, Empowering for Youth in or at-risk for foster care (SiHLE-YFC).	Boustani et al., 2017	Longitudinal: Pre-post with one month follow-up	Adapted intervention: Smart teens Informing, Healing, Living, Empowering for Youth in or at-risk for foster care (SiHLE-YFC). Four 90-minute sessions focused on increasing sexual health knowledge, improving attitudes towards and self-efficacy of condom use, and developing core skills such as problem-solving and communication.	36 youth in or at-risk of foster care. 55% male. Age 13- 17yrs (Mean = 14.96)	• Youth demographics & sexual history • HIV prevention knowledge (α = 0.68) • Condom attitudes & sef-efficacy scale (α = 0.68) • Problem oriented screening instrument for teenagers HIV/STD risk • Perceived consequences of teenage childbearing scale (α = 0.80). • Teen attitude pregnancy scale (α = 0.73) • Social problem-solving inventory for adolescents (α = 0.93) • Satisfaction scale.	Post-intervention, youth satisfied with intervention, showed improvements in sexual health knowledge (d = -1.08) & attitude towards condoms (d=0.16), & decrease in risky sexual behaviour (d=0.26). No impacts on attitudes to teen pregnancy (d= -.07), teen parenting (d=0.02) & problem solving (d= -0.02). Follow-up (available for 17/36 participants). Compared to baseline, increase in sexual health knowledge (d= -.171), decreased sexual risk taking (d=0.82). Attitudes towards condom use improved but marginally significant (d=.32).	US
3	Power through choices	Oman et al., 2016	Longitudinal RCT: residential homes from same region	Intervention (Power Through Choices [PTC]) is a 6-week, 10-session sexual health education program. PTC includes modules on skills building, role modelling, identification	1,037 youth from 44 residential homes across 3 states (foster care or juvenile justice)	• Knowledge • Attitudes • Self-efficacy	• Implementation rate was 100%. Youth attended 87% of sessions. • No significant differences between intervention & control group at baseline regarding core assessments or demographics	US

			randomised to intervention or care as usual. No significant differences at baseline in demographics or sexual behaviour.	& reduction of barriers to change, goal setting, & self-efficacy (postponing initiation of sexual intercourse; contraceptive & condom use for those who are sexually active). Data collected at pre-, post- (6weeks), 6-month, & 12-month follow-up from the intervention & control group homes Most (61.3%) homes served both child welfare & juvenile justice youth, 20.5% serve juvenile justice youth, & 18.2% served child welfare youth only. Nearly, 60% (N = 26) of homes served males only, 30% (N = 14) served females only, & fewer than 10% (N = 4) were co-ed. In co-ed group homes, intervention sessions were still conducted in gender-specific groups.	78% male. Age 13-18yrs (Mean= 16yrs)	• Intentions regarding sexuality, condom use, contraceptives & sexual behaviour	• Compared to the control group, youth in the intervention showed significantly greater improvements ($p < .05$) from pre-intervention to post-intervention in knowledge, one of two attitude areas (support for methods of proection),self-efficacy areas, & behavioural intention to use condom/method of birth control	
		Oman et al., 2018					• At 6-months, those in intervention had significantly lower odds of having sexual intercourse in the past 3 months without using birth control than those in control group (AOR = 0.72), although this effect did not remain significant at the 12-month assessment. • At 12-months, those in intervention had significantly lower odds of ever being pregnant or getting someone pregnant compared with those in the control group (AOR = 0.67).	US
		Green et al., 2017					• PTC intervention can have positive long-term knowledge and psychosocial effects regarding contraception methods on youth in out-of-home care. • Compared with control group, youth in intervention demonstrated significant improvements in knowledge about anatomy & fertility (adjusted odds ratio [AOR] = 1.07), HIV & STIs (AOR = 1.03), & methods of protection (AOR = 1.06), as well as self-efficacy regarding self-efficacy to communicate with a partner (AOR = 1.14), plan for protected sex & avoid unprotected (AOR = 1.16), & where to get methods of birth control (AOR = 1.13) 12 months after the intervention.	US
4	Making Proud Choices! (MPC) For Youth in Out-of-Home Care (MPCOOH)	Taylor et al., 2020	Longitudinal feasibility of MPCOOH (intended for out-of-home youth ages 12–18 years in a school-based or community setting). Baseline survey with post-test, &	Adapted from Making Proud Choices (MPC). MPCOOH contains two additional modules include instruction on healthy relationships and sexuality 8-hour manualised curriculum targeted at minority youth (Jemmott et al., 2002; 2016). Core elements include STI & pregnancy prevention, sexual & reproductive health attitudes & beliefs, communication, social problem solving, & sexual behaviour self-efficacy	79 workshop attendees in extended foster care (54 completed pre-training & 3-month follow-up, & 48 of those also completed post-training survey. 18-23yrs (M=21yrs), 70% female, previously or currently foster care youth participating in foster care services. Gender	• Knowledge (pregnancy, birth control, STIs, healthy relationships) • Condoms & contraception • Attitudes • Self-efficacy • behaviours	• implementation fidelity: 95% of activities completed • differences in delivery (weekly for 4 weeks; 3 consecutive days) • Participants provided positive feedback • Significant improvement in sexual & reproductive health knowledge, birth control familiarity, attitudes, and self-efficacy, post-intervention. • Knowledge of contraceptive methods & sexual health & safety in social media/technology all higher at both post-intervention time points ($p \leq 0.001$). • Level of familiarity with birth control methods higher post-intervention & at 3 months ($p < 0.001$) • Attitudes measures increased from pre to post-intervention; this increase was statistically significant for positive attitudes toward condoms ($p = 0.001$) & all attitudes combined (10 questions; $p = 0.002$), & these	US

			3-month follow-up	Includes role-play, games, & small group work, & discussions.			were still elevated from baseline to 3 months (p=<0.001). Other attitudes (i.e., about STI & pregnancy) increased post- intervention, but not statistically significantly, and had diminished at 3 months. • Self-efficacy measures increased from pre- to post-intervention, though this effect diminished at 3 months.	
5	*Making Proud Choices!* OR *Be Proud! Be Responsible!*	Combs et al., 2019	Pre-post design with post-assessments at end of training/ curriculum cycle	*Making Proud Choices!* & *Be Proud! Be Responsible!* *Making Proud Choices!* includes 8sessions, *Be Proud! Be Responsible!* includes 6 sessions. Training cycle define as delivery of fully curriculum. Each session is approximately 1-hr delivered over 6 to 8 weeks; however, the curriculum was delivered in 1-day in JJ settings.	803 youth from Foster care (FC, n = 72) & juvenile justice (JJ n=731) Age 11-19 (M = 15.48)	sexual health knowledge, and attitudes towards using condoms and birth control, knowledge related to condom use, pregnancy prevention, and STIs measured overall sexual health knowledge.	sexual health knowledge increased significantly pre to post-test among youth in FC settings (t = 9.86, df = 59, p < .001) & JJ settings (t = 17.19, df = 658, p < .001). Attitudes towards using condoms & birth control significantly improved from pre- to post-test among youth in the JJ settings (condoms: t = 3.32, df = 638, p<.001; birth control: t = 7.52, df = 614, p<.001), but not FC settings.	US
6	Peer mentoring	Mezey et al., 2015	Pilot study Phase I & II longitudinal RCT of a peer mentoring intervention for LAC.	Recruitment & training of mentors; randomisation & matching of mentors to mentees; & 1-year individual peer mentoring • 3.5-day training programme for mentor, with a booster session 4 months later. • Mentor required to meet mentee on a regular basis (1/wk) to offer support & deliver information around sexual relationships. • Intervention designed to last for 1 year but most relationships ended prematurely	26 LAC (women) aged 14–18 years (mentees/ care as usual) and 19–25 years (mentors)	Primary outcome: pregnancy in LAC aged 14–18 years. Secondary outcomes: sexual attitudes, behaviour and knowledge; psychological health; help-seeking behaviour; locus of control; and attachment style.	The study did not aim to detect intervention effects and lacked both statistical power and intervention duration to be able to do so. However • qualitative data indicative of improved self-esteem & decision-making in intervention group, especially around social networks and education • None of participants became pregnant in the year between baseline and the 1-year follow-up. The programme was acceptable & feasible, & could be manualised & replicated, but not without addressing some of the systemic/organisational & structural issues/barriers • Mentees valued intervention but had difficulty in meeting weekly as required. Only 1/4 of relationships continued for 1 year.	UK

Supplementary Materials

Supplementary Table S1. Example Search Query (Web of Science)

Number	Search Strategy: Query box: All Fields	Date	Number results
#1	("Adolescent"[Mesh] OR "Young Adult"[Mesh] OR "Young people" OR "young person" OR youth OR Teen* OR "Young adult" OR adolescent) AND ("Care Leavers" OR "Care Leaver" OR "Statutory care" OR "Looked After Children") Filter Date: 2002/01/02 – 2023/01/01	**17/06/22**	**524**
#2	"Contraception"[Mesh] OR "Condoms"[Mesh] OR "Contraceptives, Oral"[Mesh] OR "Contraceptives, Postcoital"[Mesh] OR Contraception OR Contracept* OR Condom* OR LARC OR "Long-Acting Reversible Contraception" OR Pill OR "Emergency contraception"	**17/06/22**	**85,706**
#3	"Abortion, Induced"[Mesh] OR "Mifepristone"[Mesh] OR Abortion OR Abort* OR "Termination of pregnancy" OR Mifepristone	**17/06/22**	**61,386**
#4	"Pregnancy"[Mesh] OR "Prenatal Care"[Mesh] OR "Postnatal Care"[Mesh] OR "Pregnancy and birth" OR Preg* OR antenatal OR Ante-natal OR Prenatal OR Pre-natal Or Peri-natal OR Postnatal OR Post-natal	**17/06/22**	**601,024**
#5	"Parents"[Mesh] OR "Mothers"[Mesh] OR "Fathers"[Mesh] OR Parenthood OR Parent* OR Mother* OR Father* OR "Out of home care" OR "removal of child*"	**17/06/22**	**796,647**
#6	"Psychosocial, Intervention"[Mesh] OR Intervention OR Treatment OR Program* OR Course OR "package of care"	**17/06/22**	**11,987,808**
#7	#2 OR #3 OR #4 OR #5	**17/06/22**	**1,392,242**
#8	#1 AND #7 AND #6	**17/06/22**	**91**
Filter	**#1 AND #7 AND #6** and **Articles** or **Review Articles** or **Early Access** (Document Types)	**17/06/22**	**88**
Filter	**#1 AND #7 AND #6** and **Articles** or **Review Articles** or **Early Access** (Document Types) and **English** (Languages)	**17/06/22**	**86**
Filter	**#1 AND #7 AND #6** and **Articles** or **Review Articles** or **Early Access** (Document Types) and **English** (Languages) and Research areas	**17/06/22**	**80**

Supplementary table S2: Assessment of Quality of studies

	Ahrens et al., 2021	Boustani et al., 2017	Oman et al., 2016	Oman et al., 2018	Green et al., 2017	Taylor et al.,, 2020	Combs et al., 2019	Mezey et al., 2015
Reporting: Were the following clearly described? [Yes (Y); No (N); Not possible to determine (NPD)]								
1. study hypotheses, aims, & objectives	N (0)	Y (1)	Y (1)	Y (1)	Y (1)	N (0)	Y (1)	Y (1)
2. main outcomes	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
3. characteristics of the participants	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
4. Intervention(s) of interest	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
5. distributions of principal confounders in each group	Y (1)	N (0)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	N (0)
6. main findings	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
7. estimates of random variability for main outcomes	Y (1)	Y (1)	Y (1)	Y (1)	N (0)	Y (1)	N (0)	N (0)
8. all the important adverse events that may be a consequence of intervention	N (0)	N (0)	N (0)	Y (1)	N (0)	N (0)	N (0)	N (0)
9. characteristics of patients lost to follow-up	N (0)	Y (1)	N (0)	Y (1)	N (0)	N (0)	N (0)	N (0)
10. Actual probability values for the main outcomes	Y (1)	Y (1)	Y (1)	N (0)	Y (1)	Y (1)	Y (1)	N (0)
Reporting subtotal	7/10	8/10	8/10	9/10	7/10	7/10	7/10	5/10
External validity								
11. were subjects who were asked to participate representative of the entire population from which they were recruited?	NPD (0)	N (0)	NPD (0)	NPD (0)	NPD (0)	NPD (0)	NPD(0)	N (0)
12. were subjects who were prepared to participate representative of the entire population from which they were recruited?	NPD (0)	N (0)	NPD (0)	NPD (0)	NPD (0)	NPD (0)	NPD (0)	NPD (0)
13. were the staff, places & facilities representative of the treatments the majority of the subjects received?	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)
14. was an attempt made to blind subjects to the intervention they received?	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)
15. was an attempt made to blind those measuring main outcomes of the intervention?	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)	N (0)
16. if any of the results of the study were based on 'data dredging' was this clear?	Y (1)	Y (0)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	N (0)
17. in trials & cohort studies, do analyses adjust for different lengths of follow-up? Or in case-control studies, is the period between intervention & outcomes the same for cases & controls?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	NPD (0)	Y (1)	Y (1)
18. were appropriate statistical tests used to assess the main outcomes?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	n/a(0)
19. was compliance with the intervention reliable & valid?	Y(1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)
20. were main outcome measures reliable & valid?	Y (1)	Y (1)	Y (1)	NPD (0)	Y (1)	N (0)	NPD (0)	NPD (0)
External validity subtotal	5/10	3/10	5/10	4/10	5/10	3/10	4/10	2/10
Internal validity-confounding (selection bias)								
21. For trials and cohort studies, were patients in different intervention groups? For case-control studies, were cases and controls recruited from the same population?	Y (1)	N (0)	Y (1)	Y (1)	Y (1)	N (0)	N (0)	Y (1)
22. For trials and cohort studies, were subjects in different intervention groups? For case-control studies, were cases and controls recruited over the same period of time?	Y (1)	N (0)	Y (1)	Y (1)	Y (1)	N (0)	N (0)	Y (1)
23. Were subjects randomized to intervention groups?	Y (1)	N (0)	Y (1)	Y (1)	Y (1)	N (0)	N (0)	Y (1)
24. Was the randomized intervention assignment concealed from both patients and staff until recruitment was complete and irrevocable?	NPD (0)	N (0)	NPD (0)	NPD (0)	NPD (0)	N (0)	N (0)	N (0)
25. Was there adequate adjustment for confounding in the analyses from which main findings were drawn?	Y (1)	N (0)	Y (1)	Y (1)	Y (1)	N (0)	N (0)	N (0)
26. Were losses of subjects to follow-up taken into account?	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	Y (1)	NPD (0)	Y (1)
Internal validity subtotal	5/6	1/6	5/6	5/6	5/6	1/6	0/6	4/6
Power								
27. Did the study have sufficient power to detect a clinically important effect where the probability for a difference due to chance was less than 5%?	N (0)	N (0)	Y (1)	Y (1)	Y (1)	N (0)	NPD (0)	N (0)
Quality index total score	17/27	12/27	19/27	19/27	18/27	11/27	11/27	11/27

Note: Quality of studies was assessed using Quality Index (Downs & Black, 1998, from Wells & Littell, 2009).