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Research article

Supporting Syrian families displaced by armed conflict: A pilot randomized controlled trial of the Caregiver Support Intervention

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A B S T R A C T

Background: The impact of armed conflict and displacement on children's mental health is strongly mediated by compromised parenting stemming from persistently high caregiver stress. Parenting interventions for refugees emphasize the acquisition of parenting knowledge and skills, while overlooking the deleterious effects of chronic stress on parenting. War Child Holland's Caregiver Support Intervention (CSI) aims to strengthen parenting by lowering stress and improving psychosocial wellbeing among refugee parents, while also increasing knowledge and skill related to positive parenting. The CSI is a nine-session group intervention delivered by non-specialist providers.

Objective: We describe the findings of a two-arm pilot randomized controlled trial of the CSI with Syrian refugees in Lebanon. The primary aim was to test the feasibility of our study methodology prior to conducting a definitive RCT.

Methods: We recruited 78 families (151 parents), who were randomized to the CSI or a waitlist control group. Data were collected at baseline and post-intervention.

Results: Randomization was successful, retention was high (99 %), as was intervention completion (95 % among women, 86 % among men). Implementation fidelity was excellent. Blinding was largely, though not completely effective. The CSI group showed significantly increased parental warmth and responsiveness, decreased harsh parenting, lowered stress and distress, improved psychosocial wellbeing, and improved stress management. CSI parents reported increased child psychosocial wellbeing. Control families showed no significant change on any variable.

Conclusions: Findings demonstrate the feasibility of our methodology for a definitive RCT, and suggest that the CSI shows promise as a scalable approach to strengthening parenting in refugee communities.

Trial registration # ISRCTN33665023

There is robust evidence that armed conflict and forced migration increase the risk of both short- and long-term mental health and psychosocial problems in children (Barenbaum, Ruchkin, & Schwab-stone, 2004; Jordans, Pigott, & Tol, 2016; Reed, Fazel, Jones, Panter-Brick, & Stein, 2012). Elevated rates of internalizing and externalizing problems have been documented among children in diverse conflict-affected populations (Fernando, Miller, & Berger, 2010; Panter-Brick, Eggerman, Gonzalez, & Safdar, 2009; Reed et al., 2012). Although debate continues over the precise extent of children's psychological vulnerability in conflict, post-conflict, and refugee settings, there is a growing consensus that war and displacement constitute significant threats to children's psychosocial wellbeing and ongoing development (Bangpan, Dickson, Felix, & Chiumento, 2017; Jordans et al., 2016; Slone & Mann, 2016).

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In seeking to explain elevated rates of distress and disorder among conflict-affected children, earlier studies tended to emphasize the clinical sequalae of direct exposure to war-related experiences of violence and loss (Miller & Jordans, 2016). These studies generally found a significant dose-response relationship between severity of war exposure and level of psychiatric symptomatology or risk of psychiatric diagnosis in children as well as adults (Arroyo & Eth, 1996; Mollica, Wyshak, & Lavelle, 1987; Sack et al., 1993). They also contributed to a clinical focus on treating PTSD and other manifestations of what was generally presumed to be war-related distress (Miller & Rasmussen, 2010). More recent studies, however, have found that this etiological emphasis on direct war exposure failed to consider the complex pathways by which armed conflict impacts children's wellbeing. Estimates of the predictive power of direct war exposure were often inflated by the exclusion of key mediating variables that we now know account for a considerable amount of reported distress among conflict-affected children (Catani, Schauer, & Neuner, 2008; Fernando et al., 2010; Khamis, 2016; Palosaari, Punamäki, Qouta, & Diab, 2013; Panter-Brick, Grimon, & Eggerman, 2014; Sim, Fazel, Bowes, & Gardner, 2018). Organized violence can certainly be traumatic for children, but it also generates or exacerbates a constellation of other stressors that have powerful negative effects on their mental health and psychosocial wellbeing (Miller & Jordans, 2016; Sim, Bowes, & Gardner, 2018).

Critical among these so-called *daily stressors* is compromised parenting resulting from chronically heightened caregiver stress. Parents (in this paper, we use the term *parents* to refer to any primary caregivers of children) in war zones and refugee communities struggle not only with the psychological impact of their own experiences of war-related violence and loss, but also with a host of ongoing stressors. Examples include poverty, the loss of livelihoods and possessions, unsafe and overcrowded housing, uncertainty regarding the future, humiliating treatment by local authorities, separation from social support networks, and an inability to adequately protect and provide for their children (Betancourt, Meyers-Ohki, Charrow, & Tol, 2013; El-Khani, Ulph, Peters, & Calam, 2018; Miller & Rasmussen, 2010). For women, intimate partner violence, which has been shown to increase in refugee and other war-affected populations, represents an additional source of ongoing and often extreme stress that threatens their own and their children's wellbeing (Clark et al., 2010; Hyder, Noor, & Tsui, 2007; Wachter et al., 2018).

The adverse impact of chronic stress on parenting, and in turn on children's wellbeing, is well-established (Masarik & Conger, 2017; McLoyd, 1990; Yoshikawa, Aber, & Beardslee, 2012). Chronically stressed parents are less likely to provide their children with the kind of positive and responsive interactions that contribute to healthy psychosocial development (Biglan, Flay, Embry, & Sandler, 2012; McLoyd, 1990). Highly stressed parents are also more likely to engage in harsh and even abusive parenting, both of which increase children's risk for a variety of enduring emotional and behavioral problems (Biglan et al., 2012; Jackson & Choi, 2018). For very young children, impaired caregiving represents a significant threat to the development of secure attachments, with potentially long-term adverse consequences for their mental and physical wellbeing (Biglan et al., 2012; Yoshikawa et al., 2012).

Although the impact of persistent stress on parenting has been documented extensively among families coping with various forms of adversity, only recently has stress-compromised parenting been recognized as a mediator of the impact of armed conflict and forced migration on children's mental health (El-Khani et al., 2018; Eltanamly, Leijten, Jak, & Overbeek, 2019; Meyer, Steinhaus, Bangirana, Onyango-Mangen, & Stark, 2017; Palosaari et al., 2013; Panter-Brick et al., 2014; Saile, Ertl, Neuner, & Catani, 2014; Sim, Bowes et al., 2018). Paralleling this recognition, there is growing evidence that parents can play a powerful role in attenuating or moderating the impact of organized violence on children's mental health, by providing a supportive and structured home environment to allay the fear, sadness, and uncertainty engendered by violence and displacement (Betancourt et al., 2013; Masten & Narayan, 2012; Slone & Shoshani, 2017).

Recognition of the vital role that parents play in both mediating and moderating the impact of armed conflict and displacement on children has led to interest in interventions aimed at strengthening parenting in refugee and other war-affected communities (Jordans, Tol, Ndayisaba, & Komproe, 2013; Puffer et al., 2015; Puffer, Annan, Sim, Salhi, & Betancourt, 2017; Singla, Kumbakumba, & Aboud, 2015). Drawing on evidence-based parenting interventions developed primarily in high income countries, several humanitarian organizations have developed or adapted parent-training programs that share an emphasis on strengthening positive parent-child interactions, decreasing harsh discipline, and increasing the use of non-violent behavior management strategies. *Implicit* in this emphasis is a model that explains sub-optimal parenting primarily as a lack of relevant knowledge and skills — a deficit that can be remedied through targeted interventions. This emphasis can be seen in program curricula, and in the primary outcomes assessed in the evaluations of such interventions. In the 10-session intervention Parents Make the Difference (PMD), for example, facilitators trained groups of parents in methods of positive parenting and non-violent discipline, as well as school readiness and early childhood development (Puffer et al., 2015). Findings from a randomized control trial of PMD with 270 parents were encouraging, with a significant increase in positive parent-child interactions, positive behavior management, and a reduction in harsh parenting. The small to medium effects found in the study are comparable to those found in many parenting interventions implemented in high income countries (Barlow, Smailagic, Huband, Roloff, & Bennett, 2014; Irvine, Biglan, Smolkowski, Metzler, & Ary, 1999).

The fact that several studies have found small to medium effects on parenting knowledge and behavior suggests that this deficit model has merit; parenting is difficult, and no doubt many parents can benefit from the additional knowledge and competencies acquired in parent-training programs. However, notably absent from the emphasis on increasing knowledge and skills is a recognition of the powerful impact of chronic adversity on parental wellbeing, and in turn on parenting behavior. As noted earlier, the adverse effects of persistent adversity on parents' own wellbeing, and subsequently on their parenting, have been well established in diverse conflict-affected communities. Sim and her colleagues, for example, have done excellent work documenting the pathways from war and displacement to parental stress and distress, to compromised parenting, and finally to children's mental health among Syrian refugee families in Lebanon (Sim, Bowes et al., 2018; Sim, Bowes et al., 2018). Their research extends the seminal work of Conger and his colleagues (Conger, Conger, & Martin, 2010; Masarik & Conger, 2017) on their *family stress model* (FSM). The FSM recasts suboptimal parenting among families living in adversity not primarily as a deficit in knowledge and skill, but as reflecting the impact of chronic stress on parental wellbeing, which in turn undermines parenting quality, and ultimately negatively impacts children's

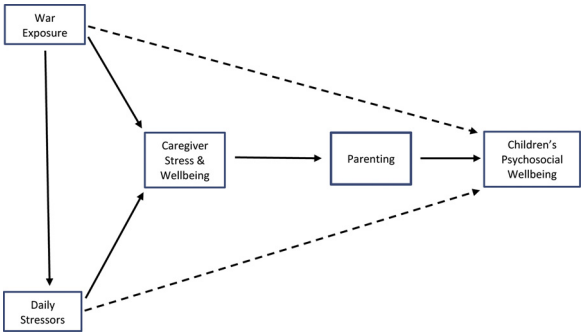

Fig. 1. Conceptual model underlying the CSI.

psychosocial adjustment. Although the FSM was originally developed to account for the effects of economic adversity on parenting, it has since found empirical support with regard to a broad range of social-ecological stressors (Masarik & Conger, 2017).

The FSM, and the support it finds in the work of Sim and her colleagues (Sim, Bowes et al., 2018), among others (Eltanamly et al., 2019), suggests that parent-focused interventions in refugee and other war-affected communities could maximize their impact on parenting, and ultimately on children's mental health and psychosocial wellbeing, by attending more substantively to parents' own needs for psychosocial support and stress management. Support for of this idea is found in the successful addition of mindfulness concepts and methods to existing parenting interventions, including the Triple P intervention with parents of children with brain injuries (Brown, Whittingham, Boyd, McKinlay, & Sofronoff, 2014), and the Strengthening Families Program, which was designed to prevent adolescent substance abuse and problem behavior (Coatsworth et al., 2015). If we start from the assumption that many refugee parents were likely caring for their children effectively before armed conflict upended their lives and drove their families into exile, our view of their current parenting struggles broadens substantially. Our explanation of sub-optimal parenting behaviour, from this view, expands from a primary focus on deficits in knowledge and skill to one which also accounts for the adverse impact of persistently high stress on caregiving. In this model, compromised parenting thus reflects the influence of two key sets of variables: (1) elevated parental distress stemming from war-related violence and loss, coupled with persistently high stress stemming from chronic adversity, and (2) parents' knowledge, attitudes, and competencies related to parenting. The latter likely also reflects a combination of socioeconomic resources, cultural norms, and personal beliefs regarding parenting and child development. This model is illustrated in Fig. 1.

It is important to acknowledge that parents appear to experience psychosocial benefits from parent-training interventions even without explicit attention to their own wellbeing (Barlow et al., 2014). This modest increase in caregiver wellbeing is largely a collateral rather than an intentional benefit, perhaps stemming from social support found in the program, as well as a greater sense of empowerment in their role as caregivers. In any case, the collateral benefits to participant wellbeing in parent-training programs are real, albeit generally small and of limited duration (Barlow et al., 2014). Whether positive changes in parenting might be strengthened by making improved caregiver wellbeing a primary aim, rather than a collateral benefit, remains to be seen.

War Child Holland's Caregiver Support Intervention (CSI) aims to strengthen parenting by lowering stress and strengthening mental health and psychosocial wellbeing among conflict-affected parents and other primary caregivers of children aged 3–12, while also increasing knowledge and skills related to positive parenting. Guided by the model in Fig. 1, we hypothesized that under conditions of lowered stress and improved psychosocial wellbeing, participants would be better able to make use of previously held as well as newly acquired parenting knowledge and skills. The intervention is described below.

This paper reports on the findings of a pilot randomized control trial of the CSI with Syrian refugee and host society families in northern Lebanon. The primary aim of this feasibility study was to assess our trial methods prior to conducting a fully powered RCT of the effectiveness of the intervention. Secondary aims were to assess the acceptability and perceived usefulness of the intervention following revisions based on feedback from a previous implementation, and to assess whether there were trends in the expected direction with regard to differences within-groups from baseline to endline.

1. Methods

Study methods and results are reported following the CONSORT guidelines on the reporting of randomized feasibility and feasibility studies (Eldridge et al., 2016).

1.1. Trial design

This was a feasibility parallel group randomized controlled trial, using a 1:1 allocation ratio. A waitlist controlled design (WLC) was employed, with families in the control group receiving the intervention upon completion of the endline assessment.

1.2. Participants

1.2.1. Inclusion criteria

- Syrian refugee and host society families with at least one child between the ages of 3 – 12. Preference was given to Syrian refugee families until the minimum threshold of 54 Syrian families had been recruited (i.e., 75 % of the target sample). This reflects Lebanese and War Child Holland requirements that interventions for Syrian refugees are also available to host-society families.
- Both caregivers were willing to participate in the study and commit to attending all nine sessions if randomized to the CSI arm. Because we were not sure whether we would be able to recruit the target number of families with parents participating, we left open the option of completing the sample, if needed, with families in which only one parent was participating.
- Both parents were willing to provide informed consent, as well as consent for the index child if the child was between seven and 12 years old (and thus eligible to complete the child self-report measure of psychosocial wellbeing).n and
- For index children between seven and 12 years old, a willingness to verbally assent to participate in the study.

1.2.2. Exclusion criteria

- Previous participation by either parent in a parenting intervention

1.2.3. Setting and locations

The study took place in the city of Tripoli in North Lebanon. As of January 2017, roughly 70,000 registered Syrian refugees were living in Tripoli; however, the actual number is widely understood to be much higher, as many Syrians have not registered as refugees with the UNHCR. A 2017 study by the Feinstein International Center at Tufts University found that approximately 75 % of Syrians in Tripoli are living below the poverty line, with a monthly income below 180,000 LBP ($120). Their living conditions are generally precarious, work restrictions are increasingly stringent, and wages are among the lowest in Lebanon (Ismail, Wilson, & Cohen-Fournier, 2017). All assessments, as well as the intervention, took place in the offices of three community-based organizations (CBOs) with which War Child Holland collaborates in the target communities.

1.2.4. Participant recruitment

Participants were recruited into the study in collaboration with the local community organizations that hosted the intervention and assessments. Specific methods included community breakfasts to announce the study, door to door recruitment in target communities, visits by outreach staff to settings where men commonly gather, and word of mouth.

1.2.5. Informed consent

Consent to participate in the study was obtained when parents came for the baseline assessment. A consent form was read aloud to them and written consent was obtained for their own participation, and for the participation of their index child if he/she was between the age of 7–12. Verbal or written assent was obtained from the subset of index children ages 7–12, who completed a self-report version of a measure assessing their psychosocial wellbeing. For children below age seven, no self-report data were collected.

1.2.6. Study timeline

The study took place between November 2017 and July 2019.

1.3. Intervention

The CSI is a nine-session weekly group intervention, co-facilitated by trained non-mental health specialists, who receive six days (42 h) of in-class training, three on-site observations with feedback, and weekly supervision with a trained social worker who is supervised by the PI and by a local Lebanese psychologist. Groups are offered separately to women and men. Table 1 lists all session topics and corresponding modules in the CSI, as well as the stress management or relaxation technique(s) taught in each session. For this study, we trained an equal number of female and male facilitators. Women's groups were co-facilitated by female facilitators, while men's groups were co-led by male facilitators.

Sessions one through four focus exclusively on caregiver wellbeing. In selecting content for these sessions, we adopted a culturally integrative approach, drawing on well-researched concepts and methods from diverse cultural contexts. Our aim was to incorporate locally salient idioms of stress and distress that reflected underlying phenomena found across cultures, thus balancing our dual aims of developing a culturally meaningful intervention that could still be readily adapted and scaled. For example, we have a session on disengaging from "thinking too much" (*Am bfakr kteer)*—a culturally salient phenomenon that both reflects and contributes to stress, roughly akin to rumination (Kaiser et al., 2015) and conceptually similar to the Buddhist concept of overthinking as a source of suffering (Kornfield, 1993). We also focus on managing anger and frustration, using the locally salient idiom of *Asabi* which refers to becoming irritable or angry in response to life stress (Miller et al., 2006). Sessions five through eight focus on strengthening parenting under conditions of adversity, and draw heavily on social learning theory and commonly used methods of training in positive parenting (i.e., increasing awareness of the impact of stress on parenting, increasing positive parent-child interactions and the use of non-violent discipline methods, and reducing harsh parenting). Session 9 entails a review and closing of the intervention. In addition, in each session participants are introduced to a new relaxation or stress management technique, drawn or adapted from the

Table 1
CSI sessions, modules, and stress management/relaxation methods.

Session	Topic	Module
1	Introduction and Group Building *SM*: Participants' own methods of coping with stress*	Caregiver Wellbeing
2	Stress and Relaxation *SM: Counting the Breath*	Caregiver Wellbeing
3	Lowering our Stress *SM: Stepping Back from our Thoughts, Grounding*	Caregiver Wellbeing
4	Coping with Frustration and Anger *SM: Peaceful Walking, various anger management techniques*	Caregiver Wellbeing
5	Parental Stress and Influence *SM: Stepping Back from our Thoughts (repeat)*	Parenting in Adversity
6	Increasing our Influence as Parents, Part I: Positive Attention *SM: Guided Visualization: A Safe Place*	Parenting in Adversity
7	Increasing our Influence as Parents, Part 2: Effective Discipline *SM: Informal Breathing Practice*	Parenting in Adversity
8	Positive Parenting: Practice *SM: Participants Choose Any Stress Management/Relaxation Method*	Parenting in Adversity
9	Looking Back, Looking Forward	Closure

* sm = stress management/relaxation technique taught during the session.

mindfulness and stress management literatures. These techniques are also provided to participants in Arabic on mp3 files, which they can either play on their smart phones or on mp3 players provided at the start of the program. Participants are encouraged to practice any relaxation or stress management activity at least three times each week. A considerable amount of time is spent each session reviewing the home practice and collectively problem-solving any barriers to practicing the techniques. For a more detailed discussion of the development of the CSI and its theoretical underpinnings, see Miller et al., n.d.

All sessions were held in the offices of community-based organizations in the target communities. Childcare was provided for a maximum of 2 children per participant. Participants were reimbursed a set fee of $5.00 USD for the cost of transportation to and from the sessions. This amount was set in consultation with our Lebanon-based team, and was designed to cover the cost of transportation, without becoming an inducement on its own to participate in the study.

1.3.1. Implementation fidelity

CSI group facilitators completed a fidelity checklist immediately after each session, indicating whether each activity planned for the session was completed, and if not, why not. There is also a comments section on the checklist, where facilitators can describe any difficulties they encountered, as well as any positive comments or suggestions about the session. The field supervisor also conducted three observational visits to each CSI group, and completed the same fidelity checklist for each session she observed. *Inclusion of Men*

A common refrain in research on parenting interventions, particularly in low- and middle-income countries, is the importance of including fathers *in future research.* Parenting programs typically include a disproportionate number of mothers relative to fathers, reflecting the general difficulty of engaging male caregivers in parent-focused interventions as well as biases at the policy and programmatic levels that prioritize women as the primary caregivers of children (Panter-Brick, Burgess et al., 2014; Pruett, Pruett, Cowan, & Cowan, 2017). However, given the powerful influence of fathers on children's psychosocial development (Cabrera, Volling, & Barr, 2018; Maselko et al., 2019; Ramchandani et al., 2013), efforts to include men in parent-focused interventions are clearly indicated.

We therefore sought to minimize barriers to men's participation in the CSI, and to make the intervention appealing to male as well as female parents, in order to maximize the impact of the program. Interviews with community members as well as the staff of local community-based organizations (CBOs), together with the expertise of our own Lebanon-based team, yielded several strategies: scheduling assessments and CSI groups on days and at times that did not conflict with income generating opportunities for men; emphasizing the focus of the intervention on personal wellbeing as well as parenting; using male outreach workers to recruit male participants; and, in the pilot study described in this paper, requiring both caregivers' participation as an inclusion criterion, which led many women to actively encourage their husbands to participate. We also conducted focus groups with male participants throughout the iterative development process, continually incorporating men's feedback in ways that increased their satisfaction and engagement with the program. Collectively, these strategies have led to the successful recruitment and retention of men in all cycles of the CSI implementation during its development and testing, a point to which we return below.

1.4. Outcomes and measures

1.4.1. Development of new measures and piloting of existing measures

We developed three new measures for this study: Caregiver Stress, Stress Management, and Parenting. All items on the new questionnaires were written in English, reviewed by a panel of experts, translated into Arabic and back-translated into English, with all discrepancies resolved through a consensus process among bilingual project staff. The items were then assessed for ease of understanding and acceptability through a process of cognitive interviewing with groups of Syrian caregivers from the target

community. All items were deemed acceptable and were readily understood. Minor wording changes were made to several items to ensure the intended meaning was conveyed. This same process of translation and cognitive interviewing was also undertaken with the other questionnaires in the study. All measures were then administered to a group of 50 caregivers on two occasions, one week apart, to assess their internal consistency and test-retest reliability.

An additional cognitive interviewing process was conducted with a group of 50 Syrian children, ages 7–12, to ensure the ease of understanding and acceptability of items on the Kindl child self-report, which was administered to index children ages 7–12.

All psychometrics in the following measure descriptions come from the baseline assessment, with the exception of the test-retest reliability coefficients, which come from the measure development and adaptation study just described.

Parenting. Parenting was assessed using a new 24 item measure developed for this study. Answer choices include *rarely*, *sometimes*, or *often*, with total scores ranging 24 − 72. In addition to yielding a total parenting score, the measure includes subscales assessing parental warmth and responsiveness (14 items) and harsh parenting (five items). Internal consistency of the full measure in in this study was good (α = .87), as it was for the warmth-responsiveness and harsh parenting subscales (α = .84 and α = .76, respectively). Test-retest reliability of the full scale was acceptable: (ICC = .67, 95 % 95 % CI: .49–.79). It was good for warmth-responsiveness subscale (ICC = .77, 95 % CI: .62–.86), and acceptable for the harsh parenting subscale (ICC = .69, 95 % CI: .51–61). The parenting measure also includes a separate 15 item scale assessing knowledge of positive parenting methods and early childhood development. It is scored separately from the other items on the parenting questionnaire, using a simple True/False answer choice option. Possible scores range from 15 − 30. Test-retest reliability was on the low side (ICC = .48, 95 % CI .09–.70).

Caregiver Stress. Caregiver stress was assessed with an 8-item scale developed for this study. Answer choices include rarely, sometimes, or most of the time, with total scores ranging from 8 − 24. The scale demonstrated good internal consistency (α = .75), and showed good test-retest reliability (ICC = .86, 95 % CI: .75–.92).

Caregiver Psychosocial Wellbeing. The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (Stewart-Brown & Janmohamed, 2008; Tennant et al., 2007) is a 14-item measure of psychosocial wellbeing that has been used extensively in cross-cultural mental health research, and has demonstrated good psychometrics in diverse populations. It has five answer choices, ranging from never to *all of the* time. Total scores can range from 14 − 70. The internal consistency of the WEMWBS in this study was good (α = .72). Test-retest reliability was also good (ICC = .78, 95 % CI: .61–.88).

Caregiver Psychological Distress. The Kessler Psychological Distress (K10) (Kessler et al., 2002) is a widely used 10-item measure of psychological distress. The five response choices range from never to *all the time,* with possible scores ranging from 10 − 50. It has been used extensively in cross-cultural clinical and epidemiological research, and has demonstrated excellent psychometrics in diverse populations. It showed a high level of internal consistency (α = .88) and convergent validity in a recent study of adults in Palestine (Easton, Safadi, Wang, & Hasson, 2017). The internal consistency of the K10 in this study was very good (α = .86), and test-retest reliability was acceptable (ICC = .74, 95 % CI: .59–.85).

Stress Management. Stress management was assessed using a 10-item scale developed for this study. Answer choices include *rarely*, *sometimes*, or *most of the time*, with total scores ranging from 10 − 30. Internal consistency in this study was good (α = .76), and test-retest reliability was acceptable (ICC = .72, 95 % CI: .52–.84).

Child Psychosocial Wellbeing-Parent Report. Children's psychosocial wellbeing was assessed with the Kid-KINDL for Parents (Ravens-Sieberer & Bullinger, 2000) for index children 7 and older, and the Kiddy-KINDL for Parents for children 3 − 6. The four school items were dropped to make the two versions identical, and four optional mental health items were added, to yield a total of 24 items. The five answer choices range from never to *all the* time, and total scores can range from 24 − 120. Because mothers spend considerably more time than fathers with children in Syrian culture, only female caregivers were asked to complete the Kindl. Internal consistency of the parent-completed Kindl was good (α = .83), and test-retest reliability was acceptable (ICC = .76, 95 % CI: .59–.86). We also used the child-self report version of the Kid-Kindl with index children between the ages of 7 and12. The child self-report version showed good internal consistency (α = .85) but only marginally acceptable test-retest reliability (ICC = .53, 95 % CI: .30–.70).

1.5. Data collection

All measures were administered twice: at baseline and again at endline during the week following the last session (10 weeks post-baseline). Data collection was conducted separately for women and men in each community. Each individual parent assessment lasted approximately 20 − 30 min, while the assessment with children (ages 7–12) lasted about 5 min. Questionnaire data were gathered using tablets, using the software program Kobo, which allows questionnaires to be completed and uploaded without paper and pencil. Kobo is available free of charge from the Harvard Humanitarian Initiative (https://www.kobotoolbox.org/). Measures were administered individually by trained and supervised research assistants. Focus group discussions were held with each CSI group after the intervention was completed. The findings of the FGDs are summarized briefly below, and are reported in depth in a separate paper (Miller, Ghalayini, et al., under review).

1.6. Sample size

Because our aim was not to assess the effectiveness of the CSI in this pilot study, we did not conduct a power analysis to determine the sample size. Rather, our aim was to recruit enough families, with both parents participating, to allow us to assess the adequacy of our study methodology (recruitment, randomization, retention, etc.). To this end, we aimed to recruit 72 families for this study, with a minimum of 75 % of them Syrian and the remaining families Lebanese and Palestinian, in keeping with the policy of the Lebanese

Table 2
Demographic Characteristics of the Sample Given in Percentages.

		CSI (n = 78)	WLC (n = 73)	Total (n = 151)
Relationship IC*	Mother	52.6	47.9	50.3
	Father	47.4	47.9	47.7
	Grandmother	0	1.4	0.7
	Grandfather	0	1.4	0.7
	Other relative	0	1.4	0.7
Type home	Apartment	38.5	38.4	38.4
	House	55.1	53.4	54.3
	Tented settlement	0	1.4	0.7
	Other	6.4	6.8	6.6
Highest education	No schooling	5.1	1.4	3.3
	Primary	37.2	31.5	34.3
	Secondary	32.1	30.1	31.1
	High school	14.1	20.5	17.2
	Vocational	7.7	4.1	6.0
	University	3.8	12.3	7.9
Working	Yes	39.7	31.5	35.8
	No	60.3	68.5	64.2

* Note: IC = index child.

government WCH of making all of its programming available to host society families. This would allow us to randomize 36 families into the CSI arm and 36 families into the WLC arm. This in turn would yield three women's CSI groups and three men's CSI groups of 12 individuals each. Three neighborhoods in Tripoli were selected for the study, and recruitment was conducted in collaboration with community-based organizations in each neighborhood with which WCH has partnered during the Syrian crisis. Recruitment took place through various means: a breakfast to which prospective participants were invited, announcements in each of the local CBOs, and outreach staff going door to door to explain the study.

A total of 72 families were recruited in which both caregivers agreed to participate. In addition, seven families were recruited in which both parents agreed to participate, but only one showed up for the assessment (for cultural reasons, women and men were assessed on separate occasions). A decision was made to retain these seven families with only one participating parent in the study, yielding a total of 79 families, and 151 parents.

Of the 151 caregivers, 87 % were Syrian refugees, 10 % Palestinian refugees, and 3% Lebanese. There were 79 women and 72 men. Table 3 shows the baseline demographics of the sample, which were quite similar between the CSI and WLC groups.

1.6.1. Selection of the index child

When a family had more than one child between the ages of 3 and 12, the research coordinator selected one child at random from the eligible children in the family, by rolling a die (with two potential index children, a roll of one, two, or three meant child A, while four, five, or six meant child B). No effort was made to stratify the sample by index child age or sex, in order to allow us to assess the distribution and determine whether stratification would be necessary in the fully powered RCT. The distribution of index children by age and sex was adequately balanced to justify not stratifying our sample in the fully powered RCT. See Table 2.

1.7. Randomization

After completing the baseline assessment, families were randomized to either the CSI or WLC arm of the study. Randomization was done at the family level to ensure that caregivers from the same family could not be assigned to different arms of the study. To facilitate understanding and acceptance of the randomization process, we adapted the methodology successfully used by Panter-Brick et al. (2018) in their research with Syrian families in Jordan. After participants had completed the baseline assessment, our research coordinator explained the randomization process to participants, inviting them to draw a lollipop out of an opaque bag containing an equal number of red and green lollipops, corresponding to the number of participants at the assessment. Baseline assessment took place over five days at the three CBOs, so this process was repeated several times. The first caregiver to be assessed from each family drew the lollipop that determined that family's group assignment. Once all data were collected from the full sample, the group assignment represented by each color was determined by a coin toss done by a WCH staff member based in Amsterdam who was unaffiliated with the study. This yielded 42 families (78 individuals) in the CSI arm, and 36 families (73 individuals) in the WLC arm.

Table 3
Age and gender of index children.

	Girls	Boys	Total
Age group 3–7 years	17	26	43
Age group 8–12 years	16	20	36
Total	33	46	79

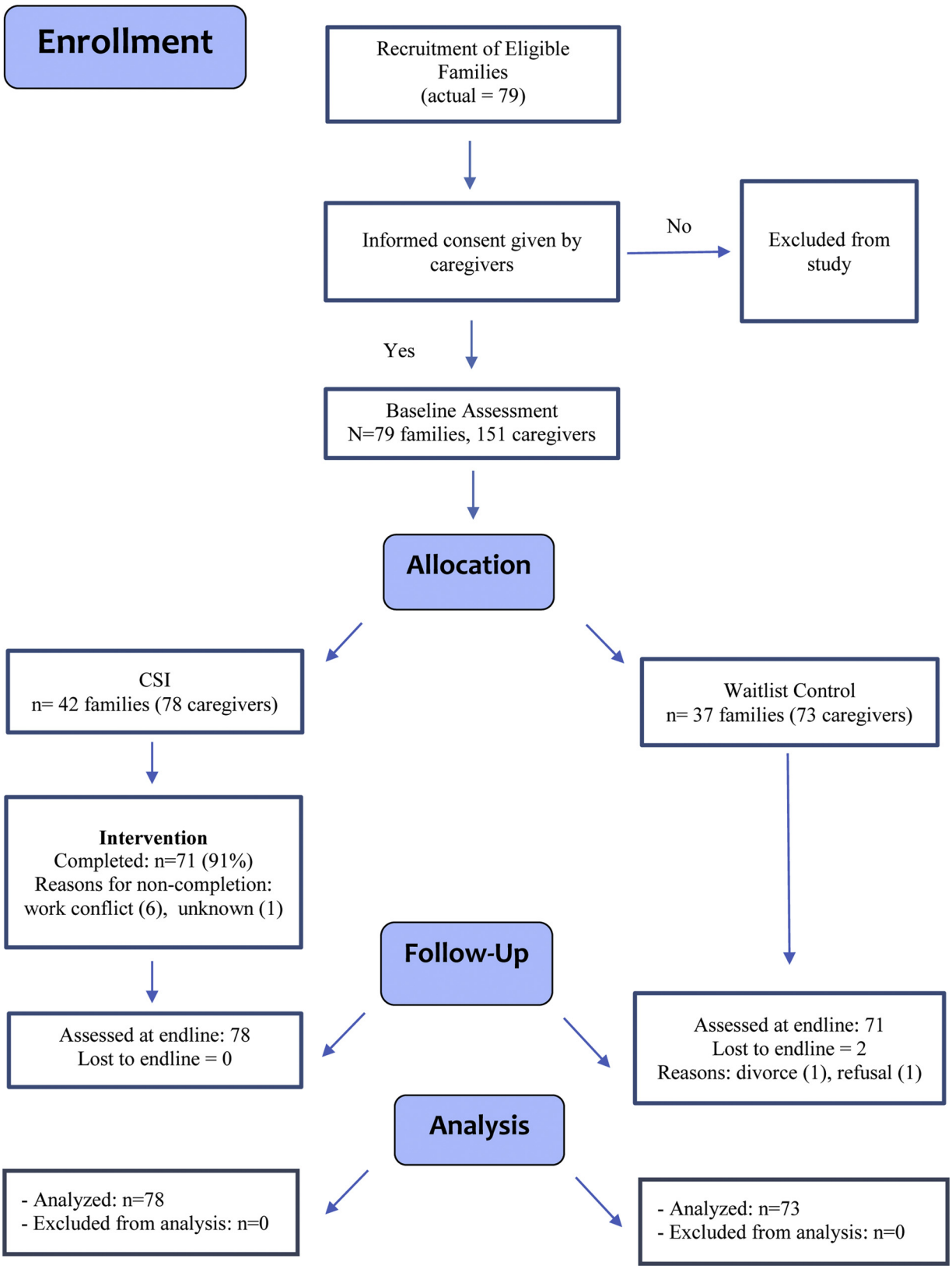

Fig. 2. Participant Flow Chart.

From this, we created seven CSI groups: four for women and three for men (see Fig. 2). The greater number of CSI families was the result of an incorrect number of lollipops of one color in the bag during one assessment session.

Randomization resulted in balanced groups on demographic and outcome variables. A between-groups *t*-test was conducted following randomization, and we found no significant differences on any demographic or outcome variable.

1.8. Blinding

The PI, co-investigators and research assistants remained blind throughout the study. The Lebanon-based research coordinator was not blind, nor, by necessity, were participants blind to their group assignment. At endline, the research assistants were able to guess at better than chance which group caregivers were in, guessing correctly approximately 65 % of the time, which they attributed to the more positive responses of CSI participants on the wellbeing and parenting questionnaires (only two of the 149 participants at endline revealed their group assignment during the assessment). We note that the Consort guidelines for pilot and feasibility trials (Eldridge et al., 2010) caution against using this method of assessing blindness, as they believe it assesses intervention effectiveness rather than blindness to group assignment. For that reason, we will not include this question in the definitive RCT.

1.9. Statistical analyses

Although our primary aim was to assess the feasibility of the methodology for a full RCT, we also ran paired samples t-tests to check whether there were within-group differences pre and post intervention in the direction we expected for the CSI and WLC groups separately, using an intent-to-treat design. The calculated effect sizes from these analyses were subsequently used as input for the sample calculation of the full RCT.

1.10. Nested qualitative study

The CSI has gone through several iterations of implementation and revision based on feedback from participants and facilitators, a process described in a forthcoming paper on the development of the intervention (Miller, Ghalayini, et al., under review). Because the version of the CSI implemented in this feasibility study included several changes based on feedback from the previous implementation cycle, we conducted focus groups with all CSI participants following the last session of the study to assess the perceived usefulness and acceptability of the revised intervention.

2. Results

2.1. Primary outcome: feasibility of study methodology

2.1.1. Recruitment, retention, and completion

As can be seen in Fig. 2, recruitment of 72 families with both caregivers willing to participate in the study was successful. Retention of participants in the study was excellent: of the 151 caregivers who completed the baseline assessment, 149 or 99 % completed the endline assessment. Completion of the CSI, defined as attending at least seven of the nine sessions, was also excellent; 95 % of the women and 86 % of the men in the CSI arm completed the intervention. The majority of completers attended all nine sessions (68 % of women and 57 % of men). Reasons for missing sessions included illness (self or a family member), work conflicts, and the wedding of a family member. Inclement weather also led to several participants missing a session.

The feasibility of other key elements of the study methodology (e.g., randomization, blinding, and implementation fidelity) has already been described earlier. In the Discussion section, we consider how the overall success of the methodology, as well as the flaws we identified, served to inform the design of the definitive RCT of the CSI that is currently underway.

2.1.2. Implementation fidelity

A review of the checklists indicated that all activities were implemented as designed in six of the seven groups. In one of the men's groups, however, the facilitators were initially insufficiently prepared and failed to implement two activities in each of the first two sessions. It was apparent from the in-session observations that some facilitators needed extra support in preparing the sessions to ensure good time management, a solid grasp of session content, and the management of group dynamics. This additional support was provided by the field supervisor. In our view, the observations, which also included a competency checklist, were critical in helping us identify which facilitators needed additional support and what skills they needed to further develop. This same observation method will be used in the definitive RCT.

2.2. Secondary outcomes

2.2.1. Acceptability of the CSI and readiness for evaluation: Focus Group Discussions

Focus groups with participants following the intervention indicated that they strongly valued the social support they found in the groups. As we describe in a forthcoming paper on the development of the CSI, both male and female participants made good use of the relaxation and stress management techniques, which they linked to improved well-being and more positive interactions with their children and spouses. Specifically, they reported that a combination of improved wellbeing and the ability to lower their arousal

Table 4
Means, Standard Deviations, Difference Scores, 95 % CIs, and Effect Sizes of Outcome Measures (n = 151).

		Baseline	Endline	M_{diff}	95 % *CI*	Cohen's *d*
Stress	CSI	19.79 (3.19)	17.23 (4.69)	−2.56	−3.46, -1.65	0.65
	WLC	18.86 (3.56)	18.34 (3.97)	−0.51	−1.34, 0.31	0.15
Psychosocial Wellbeing	CSI	49.52 (7.27)	52.44 (7.59)	2.92	1.35, 4.49	0.43
	WLC	49.21 (6.75)	49.24 (8.56)	0.03	−1.55, 1.60	< 0.01
Psychological Distress	CSI	30.27 (7.94)	24.34 (9.49)	−5.93	−7.75, -4.12	0.75
	WLC	29.69 (8.12)	30.57 (8.19)	0.88	−0.98, 2.73	0.11
Stress Management	CSI	19.04 (3.78)	21.99 (4.55)	2.95	1.99, 3.90	0.71
	WLC	19.41 (4.17)	19.59 (3.95)	0.18	−0.56, 0.94	0.06
Parenting: Total Score	CSI	59.43 (7.65)	63.70 (7.07)	4.27	2.61, 5.93	0.59
	WLC	61.08 (6.74)	61.37 (7.29)	0.29	−0.79, 1.38	0.07
Warmth-Responsiveness	CSI	35.61 (5.16)	37.61 (4.49)	2.00	0.94, 3.06	0.43
	WLC	36.61 (4.24)	36.88 (4.39)	0.27	−0.50, 1.03	0.08
Harsh Parenting	CSI	7.55 (2.05)	6.74 (1.96)	−0.81	−1.28, -0.33	0.39
	WLC	7.44 (2.43)	7.38 (2.16)	−0.06	−0.48, 0.34	0.04
Parenting Knowledge	CSI	12.35 (1.55)	13.61 (1.31)	1.26	0.86, 1.66	0.72
	WLC	12.58 (1.66)	12.69 (1.61)	0.11	−0.31, 0.53	0.06
IC Psychosocial Wellbeing Parent Report	CSI	87.24 (11.47)	93.34 (16.31)	6.10	2.24, 9.96	0.51
	WLC	88.18 (13.92)	89.68 (14.04)	1.50	−2.33, 5.33	0.14
IC Psychosocial Wellbeing Child Report	CSI	91.15 (14.06)	93.45 (14.78)	2.30	−1.91, 6.51	0.26
	WLC	91.57 (11.73)	89.43 (11.71)	−2.14	−6.80, 2.51	0.28

*Note: IC = index child.

during situations of conflict allowed them to make better use both pre-existing and newly acquired parenting knowledge and skills. Participants also reported that the video clips we used on early childhood development led to increased positive interactions with their children as well as a reduction in harsh parenting. The length, frequency, and number of sessions were evaluated positively, as was the quality of group facilitation. The close proximity of the centers was instrumental in enabling participants to attend the sessions, as was the provision of childcare, which freed women up to participate in the intervention (Miller, Ghalayini et al., under review). After having undertaken several iterations of implementation, feedback through focus groups with participants and facilitators, and intervention revision, we determined that no further revisions were indicated and the CSI was ready for evaluation in a fully powered RCT.

2.2.2. Within-group differences

All the outcome measures were tested on normality and almost all followed a normal distribution, except for the Parenting Total measure, which was negatively skewed in this sample. Therefore, we performed a Wilcoxon signed-rank test on this measure, which gave similar results as the paired-samples *t*-test (within-group differences in the CSI group, $p < .001$ and no significant difference in the control group, $p = .603$).

Although our primary aim was to assess the feasibility of the methodology for a full RCT, we also ran paired samples t-tests on the normally distributed outcomes and Wilcoxon signed-rank tests otherwise, to check whether there were within-group differences pre and post intervention in the direction we expected for the CSI and WLC groups separately. The calculated effect sizes from these analyses were subsequently be used as input for the sample calculation of the fully powered RCT (Miller, Arnous et al., 2020). Table 4 shows the means and standard deviations at baseline and endline, the mean differences, their 95 % confidence intervals, and effect sizes for the CSI and WLC groups. There were significant changes in the hypothesized direction on all parent-reported outcomes in the CSI group, with all *p*-values < 0.01. The effect sizes are included in the table as these were used as input for the sample size calculation of the future RCT. There were no significant changes on any variable in the waitlist control group.

The child-reported outcome was also tested within-groups. The children whose parents were in the CSI group showed a non-significant increase in psychosocial wellbeing ($p = .27$) and the children whose parents were in the control group showed a non-significant decrease in psychosocial wellbeing ($p = .39$).

2.2.3. Adverse events

There were no serious adverse events during the study. There were several adverse events that led us to refer participants for medical or social services (e.g., illness, eviction); however, these were not connected with the study.

3. Discussion

Our findings suggest that the evaluation methodology tested in this pilot study was feasible and is appropriate for a definitive trial to test the effectiveness of the Caregiver Support Intervention with Syrian refugee and host society families in northern Lebanon. We were able to recruit the target number of families with both parents willing to participate in the study; in fact, men were eager to participate in the study, once they were assured that CSI groups would be scheduled on days and at times unlikely to conflict with income generation opportunities. In order to avoid the inclusion of a subset of families with only one participating parent in the

definitive RCT, as occurred in this pilot study, we decided to make the participation of both parents a strict requirement in the fully powered trial.

We were able to retain an unexpectedly high percentage of participants in the study (99 %), and completion rates by both women and men were high. Given the instability and chronic adversity faced by Syrian refugees in Lebanon, we anticipated a loss of 10–15 % from baseline to endline. The use of a WLC design may have contributed to the high retention rate, as families in the WLC group knew they would be receiving the intervention within a short time after endline data collection. An additional method we used to maintain the interest and participation of the WLC group was regular WhatsApp messages reminding them of the endline assessment and the CSI groups that would be offered to them shortly thereafter. WhatsApp messages were also used by group facilitators between sessions to remind participants of their home practice and to provide encouragement.

The innovative randomization process we adapted from Panter-Brick et al. (2017) was largely, though not wholly, successful. While it did result in equal groups (i.e., no differences on demographic or outcome variables), we realized during the study that the participatory method we used required a dedicated staff member to ensure the correct ratio of green and red lollipops was always in the bag from which participants drew their color. In the definitive RCT of the CSI that is now underway, we assigned a person to this task, and randomization was fully successful.

We can only speculate as to whether involving participants in the process by having them draw red or green lollipops from a bag helped the randomization process seem more comprehensible and less arbitrary than it might otherwise have been perceived. In a previous intervention study in the same region of Lebanon, in which a conventional randomization procedure was used that did not include a participatory component, some families expressed frustration and resentment at their group assignment, which they perceived as arbitrary and unfair (Miller et al., 2020). In contrast, participants seemed to both understand and accept the randomization process in the present study, and we have used it again in the definitive RCT that is now underway.

With regard to the within-group analysis of changes on our outcome variables, we regard the results as promising, with changes in the expected direction on all parent-completed outcome measures in the CSI group, and no significant changes on any variables in the WLC group.

As noted, this pilot study was intentionally underpowered, and not designed to assess the fit of our data with the underlying model depicted in Fig. 1. In the definitive RCT of the CSI, now underway Miller, Arnous et al., 2020), we *will* examine the extent to which changes in parental wellbeing (stress, distress, psychosocial wellbeing, and stress management) mediate the impact of the CSI on parenting, and whether changes in parenting lead to improvements in children's psychosocial wellbeing. Because our model mirrors the core assumptions of the Family Stress Model quite closely, this will in effect be an assessment of the extent to which the FSM—broadened beyond its original focus on economic stress—is useful as a framework for understanding and addressing parenting in refugee families.

We used the statistics of the Parenting scale as input for the sample size calculation of the definitive RCT, as Parenting is our primary outcome measure. Power and sample calculations were done using the STATA command "clustersampsi", assuming 90 % power and a significance level of $\alpha = .05$, leading to a required sample size of 432 caregivers (216 two-parent families) accounting for an attrition rate of 20 %. However, because each CSI group should have 12 participants, we increased the sample size to 480 caregivers (240 families).

An interesting and unanticipated finding was the extent of change on the K10 reported by participants in the CSI arm. The reduction in psychological distress was the largest effect size of any variable in the study, amounting to a roughly 20 % drop in distress. We could not locate norms or an established clinical cut-off for the K10 for Syrians; however, norms from studies in diverse cultures have found that scores above 30 indicate a high probability of a mental disorder or a very high level of distress, while scores in the 25–29 range indicate a moderate risk of a mental disorder or a high level of distress (Australian Bureau of Statistics, 2003; Easton et al., 2017). Participants in the CSI arm reported a mean change in distress from 30.15–24.31. While still in the distressed range, this reduction of distress suggests that the CSI—though not a clinical intervention—may be appropriate and helpful for highly distressed parents as well as those experiencing better mental health.

3.1. Limitations

There are several limitations to this study that should be considered when interpreting the findings, and when using the findings to inform the design of a fully powered RCT of the CSI. First, this study relied on self-report methods to assess the outcomes of interest. This may have led to a social desirability response bias. It is likely that CSI participants, who were obviously not blind to their group assignment, perceived the values of the program with regard to the outcomes of interest (e.g., a preference for warm, responsive parenting and against harsh parenting). This awareness may have influenced their responses during the endline assessment. Although we were unable to control for such potential bias, the stories of change shared in the focus groups we conducted with CSI participants following the intervention were consistent with the self-reported changes we found in the questionnaire data. Family observation is a valuable way to triangulate the findings of self-report questionnaires; however, it is a resource-intensive method and would be difficult to implement with adequate privacy in the overcrowded housing conditions in which many Syrians are living. We also considered using children's reports of their parent's behavior; however, the inclusion of index children as young as three precluded the assessment of parenting by children.

As noted earlier, our unusually high retention rate was based on a design that did not include a follow-up assessment. In the definitive RCT, we will include a follow-up assessment at three months post-intervention. This means that WLC will be required to wait substantially longer, and to complete a third assessment, before receiving the intervention. It is unclear how this will affect retention.

Based on the low test-retest reliability of the Kindl-child self-report and the corresponding difficulty of interpreting the lack of change we observed on it in this study, and the fact that only a sub-set of index children in the study were old enough to complete the measure, we chose to omit it from the definitive RCT and rely exclusively on data from parents.

Finally, in retrospect it may have been useful to set *a priori* thresholds for determining the acceptability of our study methods. Fortunately, our methods demonstrated good feasibility, with only minor issues that served to inform the design of our definitive RCT.

4. Conclusion

The results of this pilot study of the Caregiver Support Intervention suggest that our study methods are feasible and appropriate for a fully powered RCT to evaluate the effectiveness of the intervention. We had a very high level of retention, low drop-out, and positive results on all parent-completed outcomes. In the definitive RCT, we will also explore the model underlying the CSI, depicted in Fig. 1, in order to assess whether changes in parental wellbeing lead to changes in parenting. If so, this would lend support to viewing compromised parenting in refugee communities as reflecting, at least partly, the deleterious effect of persistent stress and distress among parents and other caregivers of refugee children. This in turn would underscore the importance of addressing parents' own psychosocial wellbeing as an integral part of any effort to strengthening parenting in refugee families.

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