Reach Out and Read is Feasible and Effective for Adolescent Mothers: A Pilot Study

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Abstract  Objectives The Reach Out and Read program (ROaR) is associated with increased parent–child book reading and improved language development in children. Though children of adolescent parents may have an elevated risk of language delay, ROaR has never been specifically studied among adolescent-headed families. This pilot evaluated the feasibility and effectiveness of ROaR among adolescent mothers and their children. Methods This randomized controlled pilot followed thirty adolescent mothers with children aged 6–20 months in a teen-tot clinic in downtown Toronto. At each of three consecutive well child checkups, intervention families received a new children’s book, reading-related anticipatory guidance customized to the mother’s developmental stage, counselling from a librarian, and a public library card. Control families received routine care. At baseline and study completion, all mothers completed a survey on family reading patterns and the Beck Depression Inventory-Revised (BDI-IA). Results Though regression models were not statistically significant, bivariate analyses at study completion revealed that intervention mothers were significantly more likely than controls to report reading as one of the child’s favorite activities (29 vs 0 %) and had significantly lower maternal depression scores (7.0 vs 12.5; ≥10 = clinically significant depression). Trends for all other variables, including time spent reading together and maternal enjoyment of reading, were also in the direction of benefit. This program was implemented at minimal cost and adopted permanently following study completion. Conclusions This feasible and developmentally appropriate intervention shows promise in promoting shared book reading and reducing maternal depression within adolescent-headed families, warranting investigation with larger trials.

Keywords Literacy programs · Primary prevention · Child development · Pregnancy in adolescence · Reach Out and Read

Significance

Children of adolescent mothers may have an elevated risk of language delay. The Reach Out and Read program (ROaR) is a widely-used clinical intervention known to improve child language development. This study demonstrated that the ROaR model can be feasibly implemented in primary care settings for adolescent mothers and their children at minimal cost, and may provide direct benefits to adolescent mothers (such as enjoyment of shared reading time with their children and a lower risk of maternal depression) which in turn may positively influence their children’s development. The effect sizes from this pilot should be investigated in larger trials.
Introduction

In 1985, the National Commission on Reading [1] concluded that “reading aloud by parents is the single most important activity for building the knowledge required for eventual success in reading.” Available literature suggests that parent–child book reading has a significant effect on the development of early language skills and literacy [1–7]. Parent–child book reading has been associated with improved language skills and reading achievement among preschoolers [1–3]. Moreover, quiet reading time enjoyed together by a parent and child may benefit younger children and infants through improved parent–child bonding [8] and greater motivation for the child to read once developmentally ready [9, 10].

The Reach Out and Read program (ROaR), developed in the 1980s in the USA, is a clinic-based reading intervention used in over 4000 clinics in all 50 American states [11]. The model is based on three key components provided to parents and children in a primary care setting: (1) a developmentally appropriate book at each well child visit from age 6 months to 5 years; (2) anticipatory guidance for parents about reading with their child; and (3) a literacy-rich clinic environment, which could include volunteer readers and/or posters promoting literacy. Numerous studies have demonstrated that parents who receive this intervention are more likely to read aloud to their children frequently and to report that reading is one of their favorite activities with their children, while their children demonstrate improved language development [12–27].

Notably, positive effects from ROaR appear to be greatest among low-income families [12–14, 16, 22]. Teenage mothers and their children often live in poverty; furthermore, their children may be at higher risk for language delay than the general population [28–31]. Oxford and Spieker [28] suggest that language delay in this population is due to a “poor-quality home linguistic environment.” If so, teenage mothers and their children may particularly benefit from a clinic-based reading intervention such as ROaR. To date, ROaR studies have not specifically addressed outcomes in families headed by adolescent parents. Though interventions among small experimental cohorts have shown some promise in engaging adolescent mothers to read with their children [32–34], no studies have yet examined the feasibility or efficacy of reading interventions in a clinic-based setting for adolescent mothers and their children.

In evaluating a ROaR-based intervention among adolescent-headed families, maternal depression may be an important factor to assess. Adolescent mothers are more likely to experience depression than adult mothers [35, 36]; in fact, several studies have demonstrated a prevalence of depression among adolescent mothers of over 50% [37–39]. Maternal depression is strongly associated with impaired language development in infants and young children, most likely because depression impairs a mother’s ability to be a responsive caregiver and provide adequate developmental stimulation to her child [40–44]. Depression may influence how often a mother reads to her child; however, as previous studies have indicated that ROaR improves parental enjoyment of shared book reading, a ROaR-based intervention may actually improve maternal depression.

The aim of the present study was to pilot a clinical reading intervention for adolescent mothers and their children based on the principles of the highly successful ROaR program, evaluating effects on parental reading behavior, maternal depression, and feasibility of implementation. In addition, to the best of the authors’ knowledge, this study represents the first attempt to deliver a clinical ROaR-based program in Canada. The results have implications for public health programming and may inform larger studies of language development and school readiness among the children of adolescent mothers.

Methods

Study Population and Setting

The Young Families Program (YFP) at The Hospital for Sick Children is a primary care “teen-tot” clinic for adolescent mothers and their infants. Mothers aged 12–18 years at delivery are eligible for referral to the clinic. Mothers in YFP commonly struggle with poverty, involvement from child protection services, post-traumatic stress disorder, mental health issues, strained family and partner relationships, precarious living situations, and complex medical issues in themselves and/or their infants. A recent internal review of YFP from 2011 to 2014 determined that at the time of review, mothers ranged from 13 to 20 years of age with a mean age of 17.0 ± 1.3 years, while children ranged from birth to 21 months of age with a mean age of 0.9 ± 3.2 years. Child protection agencies were actively involved with 29.5% of the children.

Dyads at YFP are followed until the child is 2 years old or until the mother is 18 years old, whichever occurs later. Families are scheduled for well child visits every 1–2 months. At each visit, children receive a comprehensive primary care assessment (history, physical, developmental screening, and an immunization update) while mothers receive reproductive health services, mood assessment, and social support as required (e.g. transportation tokens, housing resources, support for school
completion and financial aid). An interprofessional team including physicians, nurse practitioners, nurses, social workers, and interdisciplinary trainees provides care to each family.

**Study Design**

This was a randomized controlled pilot study. The study was conducted in accordance with prevailing ethical principles; the study protocol was approved by the Hospital for Sick Children Research Ethics Board and all participants provided written informed consent. All adolescent mothers who visited the YFP Clinic for well child visits between November 2012 and February 2014 with a child aged 6–20 months were eligible for inclusion. This age range was chosen to correspond with the minimum age used in previous ROaR studies and the maximum age that would allow data collection to be completed before a child graduated from the clinic at 24 months of age. Families were excluded only if a child was brought to clinic by a caregiver other than his/her mother, which is a rare occurrence in YFP. Translation services were available for mothers who did not speak English as a first language.

Eligible families were approached by a research assistant for recruitment. After each participating mother provided written consent, the research assistant verbally administered a baseline questionnaire, a 3-question study questionnaire, and the Beck Depression Inventory-Revised (BDI-IA; please see "Study Measures" below for questionnaire details). Participants were randomized into either a control group or an intervention group based on whether the mother drew an even number or an odd number from a hat.

The intervention was composed of three components, based on the three established components of ROaR (see "Introduction" above). First, in addition to routine care, a staff clinician (physician, nurse, nurse practitioner, social worker, or interdisciplinary trainee) presented the child with a new developmentally appropriate children’s book inscribed with the child’s name. All books were provided to families free of charge. Second, the clinician briefly provided anticipatory guidance on techniques for shared book reading and the benefits of reading aloud to children. Third, volunteer student librarians from the University of Toronto created a literacy-rich environment by modelling shared book reading with families in their examination rooms, counselling and troubleshooting with mothers about reading techniques, informing mothers about local library services and literacy support programs, and signing each child up for a public library card in his/her name.

Intervention group families received all three components of the intervention at each of three consecutive well child visits. Control families received routine clinical care for three well child visits. After the third visit, all families again completed the 3-question study questionnaire and the BDI-IA. Upon completion of final data collection, control families were “caught up” by providing them with three free children’s books, developmentally appropriate anticipatory guidance from a clinician, a public library card in the child’s name, and a visit from a volunteer student librarian.

This intervention built on previous ROaR studies by integrating an understanding of adolescent development and the unique challenges faced by adolescent mothers into the widely used ROaR model. Prior to the intervention, clinicians participated in a 1-h information session with the investigators to discuss counselling strategies to use with the adolescent mothers when providing anticipatory guidance about reading, based on key principles of adolescent development (please see Table 1). Research assistants were also coached to be mindful of adolescent developmental needs when approaching mothers for recruitment. As adolescent mothers frequently face criticism about their parenting abilities, clinicians were particularly careful to use a strength-based approach and praise the mothers for competent caregiving, while researchers engaged the mothers as colleagues in the research process whose feedback could improve care in the clinic.

**Study Measures**

The following demographic information was collected from all participants at baseline: maternal age and self-defined ethnicity; whether the mother was enrolled in school as well as her highest completed grade; whether the mother lived in a maternity home; whether the child attended daycare at least once per week; age of child(ren); and the number of other adolescents/adults in the home.

A 3-question survey was developed for this study using questions employed in previous ROaR studies: “What are your child’s 3 favorite things to do?”, “What are your 3 favorite things to do with your child?”, and “How many days each week do you or another caregiver at home (e.g. baby’s father, grandparent) read children’s books with your child?” This survey was completed at baseline and study completion.

The BDI-IA was also completed at baseline and study completion. The BDI-IA is a 21-item self-report inventory used as a screening tool for depression as well as a measure of depression severity [45]. The BDI-IA was chosen for this study rather than the more recent BDI-II because it was already in use at the clinic (and could therefore be used at no cost) and largely correlates with the BDI-II \((r = .93)\) [46]. A score of greater than 10 on the BDI-IA indicates clinically significant depressive symptoms. Prior to completing the BDI-IA, mothers were informed by research
staff that clinically significant depression scores, or any responses suggestive of suicidal or self-harm ideation, would be reported to their clinicians for follow-up during the same visit.

**Study Analysis**

The primary outcome measure was frequent shared book reading, defined as a caregiver (either the mother or another caregiver at home) reading at least 3 days per week with the child. Secondary outcome measures included the following: average number of days per week a caregiver read with the child, proportion of mothers who identified reading as one of their favorite things to do, maternal scores on the BDI-IA, and proportion of mothers with a score of greater than 10 on the BDI-IA.

T-tests for differences in means (continuous measures) and differences in proportions (binary measures) were conducted to examine similarity between the intervention and control groups at study initiation and study completion using an alpha level of 0.05. Outcomes of interest were analyzed using linear regression for continuous measures and logistic regression for binary measures to compare measurements at study initiation and study completion. Each regression fit controlled for (1) treatment status, (2) time (study initiation versus study completion), and (3) an interaction term between treatment status and time. Mean differences and odds ratios with 95% confidence intervals were calculated between groups at baseline and study completion for outcomes of interest.

Feasibility-related outcomes of interest included the cost of literacy resources for the program (such as books and library cards), need for additional staff to carry out the intervention, additional time required by clinicians to complete the intervention during primary care visits, and acceptability of the intervention to the adolescent mothers as evidenced by recruitment and retention rates.

**Results**

Of 31 eligible mother–child dyads who were approached for recruitment during the study period, thirty (96.8%) agreed to participate in the study. Participants were randomized into an intervention group (n = 15) and a control group (n = 15). Two dyads (one from each group) were lost to follow-up during the study; one child was apprehended by child protection services, and the other dyad discontinued care at the clinic. Twenty-eight dyads (93.3%) completed the study and were included in the final analysis (please see Fig. 1).

Baseline characteristics of participating dyads are summarized in Table 2. There were no statistically significant differences between groups at baseline. The average maternal age was 17.4 years (SD = 1.2 years) and the average child age was 9.9 months (SD = 4.4 months).
Mothers identified with a variety of ethnicities. Twenty-two mothers (79%) were currently enrolled in school or had completed school, with an average completed grade level of 10.6 (SD = 1.0). Six mothers (21%) were currently living in a maternity home. Sixteen children (57%) attended daycare at least once per week. Mothers who did not pose a threat to the child's safety were included in the intervention. The results indicate that the intervention group showed a significant improvement in reading frequency and reported reading as one of the child’s favorite activities compared to the control group.

Table 2: Baseline characteristics between experimental groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group (n = 14)</th>
<th>Intervention group (n = 14)</th>
<th>Total (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age in years [mean (SD)]</td>
<td>17.6 (1.2)</td>
<td>17.1 (1.3)</td>
<td>17.4 (1.2)</td>
</tr>
<tr>
<td>Age of child in months [mean (SD)]</td>
<td>9.8 (4.5)</td>
<td>10.0 (4.5)</td>
<td>9.9 (4.4)</td>
</tr>
<tr>
<td>Maternal race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White [n (%)]</td>
<td>3 (21.4)</td>
<td>0 (0)</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>Black [n (%)]</td>
<td>5 (35.7)</td>
<td>10 (71.4)</td>
<td>15 (53.6)</td>
</tr>
<tr>
<td>Latina [n (%)]</td>
<td>2 (14.3)</td>
<td>1 (7.1)</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>First Nations [n (%)]</td>
<td>0 (0)</td>
<td>2 (14.3)</td>
<td>2 (7.1)</td>
</tr>
<tr>
<td>Other [n (%)]</td>
<td>4 (28.6)</td>
<td>1 (7.1)</td>
<td>5 (17.9)</td>
</tr>
<tr>
<td>Highest grade completed [mean (SD)]</td>
<td>10.6 (1.0)</td>
<td>10.6 (0.9)</td>
<td>10.6 (1.0)</td>
</tr>
<tr>
<td>Currently in school or already completed high school [n (%)]</td>
<td>11 (78.6)</td>
<td>11 (78.6)</td>
<td>22 (78.6)</td>
</tr>
<tr>
<td>Child attends daycare at least once per week [n (%)]</td>
<td>9 (64.3)</td>
<td>7 (50.0)</td>
<td>16 (57.1)</td>
</tr>
<tr>
<td>Currently living in a maternity home [n (%)]</td>
<td>3 (21.4)</td>
<td>3 (21.4)</td>
<td>6 (21.4)</td>
</tr>
<tr>
<td>If NOT in a maternity home: number of other adults/adolescents in the home [mean (SD)]</td>
<td>1.8 (1.6)</td>
<td>1.5 (1.8)</td>
<td>1.6 (1.7)</td>
</tr>
</tbody>
</table>

Table 3: Primary and secondary outcome measures in the treatment groups at study initiation and study completion

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Time</th>
<th>Control (n = 14)</th>
<th>Intervention (n = 14)</th>
<th>t test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reading at least 3 days per week [n (%)]&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Initiation</td>
<td>11 (78.6)</td>
<td>6 (42.9)</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completion</td>
<td>7 (50.0)</td>
<td>9 (64.3)</td>
<td>0.46</td>
<td></td>
</tr>
<tr>
<td>Total days of reading per week [mean (SD)]</td>
<td>Initiation</td>
<td>4.1 (2.5)</td>
<td>3.4 (2.3)</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completion</td>
<td>2.7 (2.7)</td>
<td>4.0 (2.2)</td>
<td>0.53</td>
<td></td>
</tr>
<tr>
<td>Reading reported as one of child’s favorite activities [n (%)]</td>
<td>Initiation</td>
<td>3 (21.4)</td>
<td>2 (14.3)</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completion</td>
<td>0 (0)</td>
<td>4 (28.6)</td>
<td>0.04&lt;sup&gt;*&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Reading reported as one of mother’s favorite activities with child [n (%)]</td>
<td>Initiation</td>
<td>4 (28.6)</td>
<td>3 (21.4)</td>
<td>0.68</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completion</td>
<td>1 (7.1)</td>
<td>5 (35.7)</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>BDI-IA score [mean (SD)]&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Initiation</td>
<td>11.3 (10.4)</td>
<td>8.1 (4.8)</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completion</td>
<td>12.5 (7.2)</td>
<td>7.0 (4.2)</td>
<td>0.02&lt;sup&gt;*&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>BDI-IA score of &gt;10 [n (%)]&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Initiation</td>
<td>4 (28.6)</td>
<td>6 (42.9)</td>
<td>0.45</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Completion</td>
<td>8 (57.1)</td>
<td>3 (21.4)</td>
<td>0.06</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Statistically significant using an alpha level of 0.05

<sup>b</sup> Primary outcome

<sup>c</sup> BDI-IA Beck Depression Inventory-Revised

<sup>c</sup> A BDI-IA score of >10 indicates clinically significant depressive symptoms
not live in a maternity home lived with an average of 1.6 (SD = 1.7) other adolescents or adults.

Table 3 compares the primary and secondary outcome measures between the treatment groups at study initiation and study completion. Groups were similar at study initiation. By study completion, the intervention group was significantly more likely to report reading as one of their child’s favorite activities to do with their child (OR = 7.4) while control group mothers decreased their BDI-IA scores by an average of 1.2 points; thus, the average spread between the groups increased from 3.1 to 5.5 points by study completion. By study completion, intervention group mothers were less likely than controls to have a clinically significant maternal depression score.

Results from regression models, which adjusted for treatment group, time, and the interaction between treatment group and time, are reported in Table 4 as mean differences for continuous outcomes and odds ratios for binary outcomes with 95 % confidence intervals. Though no results from the regression models were statistically significant, several important trends were observed in the effect sizes. By study completion, compared to controls, intervention group mothers were over 7 times more likely to report that reading was one of their child’s favorite activities (OR = 7.4) and nearly 5 times more likely to report that reading was one of their favorite activities to do with their child (OR = 4.7). Over the study period, intervention group mothers increased their odds of reporting that reading was one of their child’s favorite activities (OR = 2.2) or one of their own favorite activities to do with their child (OR = 1.8) while control group mothers decreased their odds of these outcomes (OR = 0.2 and 0.3, respectively). Over the study period, control group mothers increased (worsened) their BDI-IA scores by an average of 1.2 points while intervention group mothers decreased (improved) their BDI-IA scores by an average of 1.2 points; thus, the average spread between the groups increased from 3.1 to 5.5 points by study completion. By study completion, intervention group mothers were less likely than controls to have a clinically significant BDI-IA score (OR = 0.3). Over the study period, the odds of having a clinically significant depression score decreased by half among the intervention group mothers (OR = 0.5) while increasing among the control group mothers (OR = 2.5).

All books distributed to families were donated by private bookstores and library cards distributed to families were donated by Toronto Public Libraries. Consequently, there was no cost to acquiring literacy promotion resources for the intervention. We established a relationship with the University of Toronto Library Sciences Program in which students acting as volunteer librarians in our clinic could
use their volunteered time towards their required practicum hours for receiving course credits. No additional staff were required to carry out the intervention. Clinicians incorporated anticipatory guidance around reading into their routine well child visits with no need for additional visits or extended clinic hours. Student librarians worked with families while they were waiting to see their clinical providers so intervention families did not require longer visits.

Discussion

This is the first study to evaluate the effects of the ROaR intervention among adolescent-headed families. The investigators modified this widely used pediatric intervention by placing an understanding of adolescent development at the core of the study’s methodology. Adolescence is a developmental stage characterized by identity development, desire for independence, immature capacity for abstract thought, and an evolving ability to think from the point of view of others [47]. In this study, anticipatory guidance about reading was deliberately customized to the developmental level of the teen mother by emphasizing the potential for direct benefits to the mother, using concrete language and concepts, empowering her to take charge of her child’s development, and praising her parenting skills while discussing how to expand them. Although regression models could not demonstrate statistical significance in this small sample, several important trends were observed. Adolescent mothers exposed to this developmentally appropriate intervention improved in all measures, including shared reading frequency, perception of reading together as one of the mother’s or child’s favorite activities, and depression scores; in comparison, the control group mothers worsened in all measures. By the end of the study period, the intervention group was superior to the control group in all measures with notable effect sizes.

Though this study did not measure developmental outcomes among the children (e.g. language and reading skills), mothers who received the intervention appear to have experienced direct benefits (enjoyment of time spent reading with their children and protection from worsening depression scores) known to be necessary ingredients for fostering attachment and developmental progress among children [48, 49].

This study’s high recruitment rate (97 %) and retention rate (93 %) are particularly noteworthy as adolescent mothers in YFP frequently miss appointments and change their contact information. This study did not investigate the mothers’ motivations for participating, but these high rates may be a result of young mothers responding positively to the study’s encouraging tone, sensitivity to their developmental stage, and efforts to engage them in the shared goal of improving outcomes in the clinic. The study intervention was feasible and delivered at little cost. All books and library resources were donated and all librarian time was volunteered by student librarians who also received course credit for their participation. Aside from research staff collecting data, no additional clinic personnel were required to implement the intervention, which took place during regularly scheduled well child visits with minimal extra time required from either clinicians or families. Stakeholders in the project, including participating families, clinicians, student librarians, Toronto Public Libraries, and supporting bookstores, were enthusiastic about the project and frequently reported a positive sense of community from their involvement. Following the success of this pilot study, the intervention was permanently adopted by The Hospital for Sick Children for all families in YFP and has received recognition as a valuable patient-centered service. The program continues to receive donations of books and literacy promotion resources, as well as volunteer placements from University of Toronto Library Sciences students, allowing it to continue operating at no additional cost.

An important limitation of this study was its small sample size, which resulted in inadequate power to establish statistical significance. The study was also implemented in a single clinic, which may limit its generalizability to other centers. Additionally, it lacked long-term follow-up of parental reading behavior and filial developmental trajectories. However, the encouraging effect sizes in this pilot study warrant larger trials involving a variety of primary care settings. Future studies could examine whether the intervention’s positive effects on adolescent mothers’ behavior are sustained over time and whether the intervention positively affects children’s developmental outcomes. Qualitative research could explore factors that motivate adolescent parents to read to their children as well as the challenges they face in doing so.

In summary, this study represents the first evaluation of the ROaR model among adolescent-headed families, whose children are known to have elevated socioeconomic and developmental risks. This program built on existing ROaR literature by considering the unique developmental stage of adolescent parents when providing anticipatory guidance about shared book reading with their children, which seems to be a key factor for success. The study demonstrates that the ROaR model can be feasibly implemented at minimal cost for adolescent-headed families in primary care clinics. The intervention may provide direct benefits to adolescent mothers, which in turn may positively influence their children’s development. The effect sizes from this pilot study should be investigated in larger trials, and public health programming should be directed toward this vulnerable population.
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Compliance with Ethical Standards

Conflict of interest  The authors have no real or potential conflicts of interest to disclose. All sources of funding are acknowledged in the preceding Acknowledgements section.

Research Involving Human Participants  The investigators subscribe to the basic ethical principles underlying the conduct of research involving human subjects as set forth in the Belmont Report. All research protocols, research questionnaires, and consent documents were approved by The Hospital for Sick Children Research Ethics Board.

Informed Consent  The nature of the study was fully explained to all potential subjects, including that it involved research, that they would be randomized to one of two study arms, the purposes of the research, the expected duration of the subject’s participation and how much time it would require, a description of the study questionnaires, a description of any foreseeable risks and benefits that could reasonably be expected, a discussion of how confidentiality of records would be maintained, that participation was voluntary with no subsequent impact on the family’s clinical care if they chose not to participate, that any question on a questionnaire could be skipped, and that participants could withdraw at any time from the study. A written consent document containing all pertinent information was provided to potential participants and verbally reviewed by research staff with an opportunity for the participant to ask questions before consenting.

References


