

A Randomized, Controlled Trial of a Community-Based Support Program for Families of Children With Chronic Illness: Pediatric Outcomes

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Background: Children with chronic illnesses have a heightened risk for mental health problems.

Objectives: To develop, implement, and evaluate child outcomes of a 15-month, community-based, family-support intervention designed to reduce risk for poor adjustment and mental health problems in children with 1 of 4 chronic illnesses (diabetes mellitus, sickle cell anemia, cystic fibrosis, or moderate to severe asthma) and their mothers.

Design: Randomized, controlled clinical trial design with multiple measures of mental health based on both child and parent reports taken 1 year apart.

Setting: Community-based intervention linked to subspecialty and general pediatric clinics and practices in Baltimore, Md.

Participants: One hundred thirty-six mothers and children aged 7 to 11 years with diabetes mellitus, sickle cell anemia, cystic fibrosis, or moderate to severe asthma.

Intervention: The program, provided by “experienced mothers” and child life specialists, included telephone contacts, face-to-face visits, and special family events.

Main Outcome Measures: Outcomes were measured using the following instruments: the Personal Adjustment and Role Skills Scale III, the Children’s Depres-

sion Inventory, the Revised Children’s Manifest Anxiety Scale, and the Self-Perception Profile for Children.

Results: The experimental group’s mean adjustment score increased over the intervention period while the control group’s mean adjustment score decreased. Analysis of variance demonstrated that the intervention had a significant main effect on postintervention adjustment controlling for baseline scores ($P = .01$). Using a cutoff score indicating maladjustment, the percentage of experimental group children in the maladjustment range fell from 19% at baseline to 10% after the intervention; the percentage of control group children in the maladjustment range rose from 15% at baseline to 21% after the intervention. The effect of the intervention was more pronounced for children who had low physical self-esteem than for those who had moderate to high physical self-esteem at the beginning of the program.

Conclusions: Our results demonstrate modest positive effects of a family support intervention in promoting the adjustment of children with selective chronic health conditions. Including child life specialists in a community-based intervention may be especially salient for children with chronic illnesses who have low physical self-esteem. The intervention had a similar outcome for all diagnostic groups, suggesting that it could be effective for children with any chronic illness and implemented in a variety of pediatric settings.

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FIFTEEN PERCENT to 18% of the children in the United States have a chronic illness or disability.^{1,2} More than 2 decades of epidemiological and clinic-based studies indicate that these children are at a heightened risk for mental health problems.³⁻⁶ Over the last 2 decades, however, pediatricians have moved from a general belief that children with chronic illnesses and disabilities are inevitably troubled to a more nuanced view that accounts for variability in outcomes based on multifactorial processes of stress and coping.⁷ Nevertheless, in view of the pre-

vailing evidence that children with chronic illnesses are at risk for poor psychological outcomes, the question remains: can this risk be lessened?

In 1997, Bauman et al⁸ reviewed studies describing the outcomes of psychosocial interventions for children with chronic illness that had been published through 1993. They reported that some interventions had modest effects in helping “children and families cope with the psychological and social consequences of chronic health conditions.”^{8(p250)} Bauman et al noted, however, that most of the studies had serious methodological weaknesses

PARTICIPANTS AND METHODS

SAMPLE IDENTIFICATION

Potential participants were identified through 11 specialty clinics and 5 general pediatric practices in the Baltimore area. An effort was made to recruit every potentially eligible family listed on the clinic or practice rosters. Families were eligible if they lived within a 50-mile (80-km) radius of Baltimore City and had a telephone, a woman was the primary caregiver and the child lived with her, the target child was 7 to 11 years old and did not have mental retardation, the diagnosis was made at least 6 months prior to recruitment, and the family spoke English. To enroll children with moderate to severe asthma, the following additional criteria were used: (1) receiving daily medication, (2) wheezing 2 to 3 times per week, or (3) having at least 1 hospital or emergency department visit in the past 6 months.¹⁸

RECRUITMENT AND DATA COLLECTION PROCEDURES

After potential participants were identified, the clinic director or pediatrician sent them a letter describing a longitudinal research project involving families of children with chronic illness, inviting them to participate if they wished, allowing them to decline to be called, and noting that otherwise someone would call them to explain the project in detail. The letter stressed that participation was voluntary.

If families agreed to participate during the follow-up telephone call, appointments were made for the interviews in the family's home. Data were collected from mothers and children in 45- to 90-minute, face-to-face, structured interviews at baseline (T1) and 12 months later (T2). At each face-to-face interview, mothers were paid \$20 for their time and children received a toy. Interviews were completed by paid interviewers who had undergone extensive training and were blind to group assignment. Informed consent statements pertaining to the research project were signed at the initial interview. All procedures were approved by the institutional review boards at Johns Hopkins Hospital and Sinai Hospital of Baltimore.

ASSIGNMENT-TO-GROUP PROCEDURES

In the recruitment letter and follow-up telephone call, participants were invited to join a longitudinal research study on families raising children with chronic illnesses. No mention was made of intervention programs until the end of the baseline interview, when the interviewer described 2 programs in which the family could participate. She explained that the mother had the opportunity to put her name "in a hat" and that families would be drawn by chance and assigned to 1 of the programs. The interviewer emphasized that the mother could still participate in the research interviews whether or not the mother decided to put her name in the hat. This design allowed us to identify

characteristics of program nonparticipants or "nonjoiners" (ie, those who would participate in the research but not in the intervention).¹⁹ Families who agreed to put their names in the hat were randomly assigned to either the experimental or control group. Mothers were sent letters informing them of their group assignment.

EXPERIMENTAL (INTERVENTION) GROUP

The intervention, referred to as the Family-to-Family Network, was designed to reduce risk for mental health problems in children with chronic illnesses and their mothers through a 15-month intervention that had 2 linked, mutually reinforcing components. One component was developed and implemented by 3 child life specialists (CLSs), and was referred to as KIDS (Kids Involved in Discovery and Sharing). This component was designed to enhance the mental health, adjustment, and self-esteem of children with selected conditions.

The activities incorporated into the KIDS program were designed by the CLSs to convey "messages" conceptually linked to specific program objectives. For example, one objective involved enhancing acceptance of one's physical appearance. Various activities were used to convey 3 messages: "What's right with my body," "What I'm good at," and "Liking how I look." Specific activities included making a scrapbook, tracing the child's body, reading books, and doing role play. Additional details regarding the intervention's theoretical framework and its application are in a manual available from the lead author.²⁰

The CLSs aimed to make 7 visits of 60 to 90 minutes to each assigned family, either in the family's home or in the community. Between these visits, the CLSs made monthly telephone calls to assigned children; sent out a monthly letter with seasonal greetings, puzzles, jokes, and related health care information; and mailed 3 newsletters with children's stories, drawings, and "advice to doctors." The CLSs also sponsored periodic lunches that involved 2 to 4 participating families and occasional bowling parties to which all enrolled families (including fathers and siblings) were invited.

The other component of the Family-to-Family Network focused on the children's mothers. A selected and trained group of "veteran" or "experienced" mothers of older children with the same target conditions were responsible for this component. This group of mothers referred to themselves as "Network Mothers (NMs)." Details regarding the recruitment, training, and support of the NMs and the conceptual underpinnings of the maternal program component are available elsewhere.¹⁷

Thus, the experimental group was offered an intervention that was implemented by a professional-parent team (ie, the CLS with the NM). Assignments of participating families to the CLS-NM teams were based on diagnosis; the NMs were assigned to families of children who had the same condition as their own children had. The CLSs and the NMs coordinated their efforts with each family, were in regular telephone contact to exchange information about

and suggested that future studies include more rigorous designs and sufficient sample sizes.

Since 1993, additional psychosocial intervention studies have been published. Some have focused on psychological issues related to medical procedures,⁹ others have

investigated effects of support interventions for families of children with a particular long-term condition,^{10,11} and one program used nurses to provide information and support to families.¹² Most of these studies reported at least modest positive effects on mental health or coping. However,

significant issues that arose during visits and telephone calls, and met weekly as a group. A pediatrician (R.G.C.) and a social worker attended these weekly meetings to ensure that the intervention was being provided as planned and to provide guidance and support to the intervention teams. The 3 CLSs also met weekly with the pediatrician. The intervention was provided to 2 cohorts from May 5, 1996, to January 31, 1999.

CONTROL GROUP

The control group program was designed to reflect a common practice in many subspecialty clinics, where a mother is given the name of another mother to call should she need support or information. The families randomly assigned to our control group were given a telephone number through which they could reach an experienced parent if they so wished. This experienced parent had no special training and did not initiate telephone calls. Children in the control group had no contact with the CLS on our project and no mention was made of the KIDS program.

MAIN OUTCOME MEASURES

Items from previous studies were used to collect demographic information (eg, family composition) and data pertaining to the child's health and functional status, including whether symptoms were unpredictable, whether the child was ever so sick that the parent thought he or she might die, and the number of days of activity limitations in the past year.^{15,16} The full list of these items is available from the lead author.

We used 3 indicators of child mental health. First, child psychosocial adjustment was measured using the Personal Adjustment and Roles Skill Scale (PARS) III.²¹ The PARSIII is a 28-item measure completed by mothers that taps children's normative roles and activities (eg, spending time with friends) as well as mild problem behaviors (eg, complaining about problems, flared up if could not have own way). This scale has good reliability and discriminant validity, no psychosomatic items, and has been used with minority populations and in diverse settings.²¹ The PARSIII has a total adjustment score and 6 subscales, including hostility, anxiety/depression, dependency, withdrawal, productivity, and peer relations. Higher scores are associated with better functioning.

Depressive symptoms were measured with the Children's Depression Inventory, a 27-item, self-report measure that reflects recent affective, cognitive, and behavioral symptoms of childhood depression.²² Scores on this measure have been shown to discriminate clinically depressed and nondepressed psychiatric patients. Internal consistency coefficients ranging from 0.71 to 0.84 and test-retest reliability estimates (0.82) are acceptable.²³ The clinical cutoff score for the upper 10% of elementary school children in a normative sample is 19.

The Revised Children's Manifest Anxiety Scale was used to assess child self-report of general anxiety.²⁴ The Revised

Children's Manifest Anxiety Scale is a 28-item measure that reflects physiological anxiety, worry/oversensitivity, and concentration problems. Internal consistency was 0.83 to 0.85, test-retest reliability over a 9-month interval was 0.68, and the scale showed convergent validity with the State-Trait Anxiety Inventory for Children.²⁵

Children's self-esteem was measured by 4 subscales from the Self-Perception Profile for Children.²⁶ Each subscale consists of 6 items. The physical appearance subscale is used to assess body esteem, and taps the degree children are happy with their appearance. The social acceptance subscale taps the perception that the child is involved in a peer group. The athletic subscale measures the amount that children feel confident in their athletic abilities. The global self-worth subscale assesses the degree to which children feel they are worthwhile persons overall; this scale has its own items and is not a sum of the other scales. Internal consistency on the subscales ranged from 0.78 to 0.84 in third to eighth grade children and test-retest reliability was adequate.²⁶ This scale has been used frequently in studies of youth with chronic illnesses.¹²

We measured "dose" of the intervention by the number of contact minutes between families and their intervention team. Over the course of the 15-month intervention, families had an average of 2 visits from their assigned NM (range, 0-6 visits), 3 visits from their assigned CLS (range, 0-13 visits), and attended an average of 1 special event (range, 0-6 events). Mothers received an average of 7 significant telephone calls (defined as lasting >5 minutes) from their assigned NM (range, 0-43 telephone calls). Their assigned CLS made an average of 3 significant telephone calls (range, 0-11 telephone calls) per child. Children received an average of 15 letters from their assigned CLS (range, 5-28 letters). The mean total time spent in program activities per family was 1378 minutes (23 hours; range, 1 hour to 80 hours). For every significant call the NMs made, they made 2 nonsignificant calls or attempts. For every significant call the CLSs made, they made 6.7 nonsignificant calls or attempts. In general, participating children led active lives and had working mothers, factors that made it difficult to find time for visits and telephone calls.

ANALYTIC PLAN

First, to test the outcome of randomization, the experimental and control groups were compared for selected child variables (including child adjustment, depression, anxiety, and condition-related variables) and demographic indices using *t* tests. Second, bivariate analyses were conducted to examine relationships among key variables (eg, demographic and condition-related variables) and main outcome measures. Third, analysis of variance was used to examine child outcome variables in relation to group status (ie, experimental or control) while controlling for baseline characteristics. Finally, we conducted multiple regression analyses to assess effects of the intervention and potential moderators on main outcome measures.

many of the same methodological problems noted by Bauman et al continue to plague the medical literature.

In addition, during the last decade, the pediatric community has placed increasing emphasis on the importance of working with families of children with long-

term conditions to create a medical home within which services can be coordinated.¹³ This approach to practice includes linking families to available, community-based, family-to-family support programs and underscores the potential value of information and support that

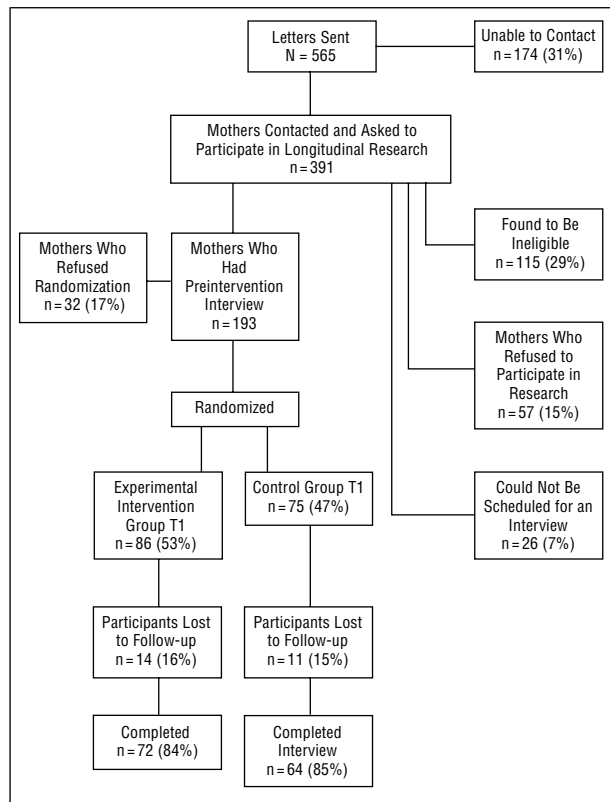


Figure 1. Study design.

families of children with similar conditions can share among themselves.¹⁴ However, virtually all of the interventions reported in the published literature rely on health or mental health professionals based in medical centers.

For the study reported herein, we aimed to develop, implement, and evaluate child outcomes of a 15-month, community-based, family-support intervention designed to reduce risk for poor adjustment and mental health problems in children with 1 of 4 chronic illnesses (diabetes mellitus, sickle cell anemia, cystic fibrosis, or moderate to severe asthma) and their mothers. We also sought to address many of the methodological issues noted by Bauman et al⁸ and to fashion a program that reflected key concepts pertaining to community-based, family-to-family support. In addition, we drew from continuing clinical experience with this population and with similar program evaluations.^{15,16}

To evaluate the effects of the program, we used a randomized, controlled clinical trial design and multiple measures of mental health based on both child and parent reports. The intervention was conceptualized and structured so that it can be provided to families of children who have any long-term condition. For evaluation we used the same mental health measures for all mothers and children, regardless of diagnosis. This article describes key components of the intervention and its effects on children. Parent outcomes are reported elsewhere.¹⁷

We hypothesized that, controlling for baseline status, children in the intervention group would have better mental health at the end of the intervention compared with children in the control group, as measured by changes in psychological adjustment, depression, and anxiety scale

scores. We also examined whether the intervention group would have more positive self-esteem scores compared with the control group, and if so, whether this change was associated with changes in scores on the other mental health measures. In addition, we tested hypotheses that the intervention would have stronger effects for children at higher risk for poor adjustment.

RESULTS

As **Figure 1** shows, 565 letters were sent to patients, inviting them to participate in the study. One hundred seventy-four (31%) were unable to be contacted (no telephone, change of address, no answer). Of the 391 families who were contacted, 115 (29%) were ineligible (based on residence, mental retardation, language difficulties, or asthma severity criteria). Fifty-seven (15%) refused to participate and 26 (7%) were unable to be scheduled for an interview within the interview period. One hundred ninety-three baseline interviews were completed.

Of the 193 mothers who were eligible for randomization, 32 (17%) refused to be randomized. The refused randomization group generally reported better functioning than both the experimental and the control groups.¹⁹ For this article, we excluded data from mothers who refused to be randomized because we undertook an intent-to-treat analysis of program effects.

Of the 161 families randomized, 86 were randomized to the experimental group and 75 to the control group. Overall, 25 families, 14 and 11 from the experimental group and the control group, respectively, were lost to follow-up, resulting in a total of 136 mother-child pairs for the analyses (72 in the experimental group and 64 in the control group). **Table 1** lists selected demographic and health status characteristics of the experimental and control groups. No baseline differences between these groups were found on key independent or dependent variables. Analysis of variance indicated that the only main outcome measure that differed for the experimental and control groups was child adjustment. **Table 2** gives baseline and 12-month postbaseline (T2) scores on child adjustment, as measured by the total PARSIII scores and subscale scores.

Using the total score, the analysis of variance demonstrated that the intervention had a significant main effect ($P < .01$), controlling for preintervention scores. The PARSIII includes 6 subscales. As data in Table 2 indicate, the experimental group's scores increased more (or decreased less) on 5 of the 6 subscales. Multiple regression analyses controlling for baseline scores showed that the intervention had significant effects on the hostility subscale ($t = -2.56, P = .01$) and the anxiety/depression subscale ($t = -3.28, P = .001$).

Another way to assess the effect of an intervention is to examine whether children fall below a cutoff score that indicates maladjustment. The PARSIII, however, lacks an established cutoff point. Adopting a method reported in a prior study,¹² we calculated a cutoff score by using the total group mean at baseline minus 1 SD. The cutoff score in this sample was 78, almost exactly the score of 78.3 used in the previous study.¹² At baseline, 19% of the children in our experimental group and 15% of the control group fell below this cutoff point. At T2, 10% of the experimental group children scored below this cut-

off point; in contrast, 21% of the children in the control group fell below the cutoff point.

We found no effect of the intervention on measures of children's anxiety, depression, or self-esteem. Only 7 (5%) of the children in our current sample scored above the clinical level on the Children's Depression Inventory. For the Revised Children's Manifest Anxiety Scale, the mean and SD in our sample is close to the normative sample.²⁵ Because there was no effect of the intervention on self-esteem, we could not test whether changes in self-esteem were linked to changes in children's adjustment.

However, we did evaluate whether high-risk subgroups of children were affected differentially by the intervention. One high-risk group that we investigated included children who had low self-esteem at baseline. We dichotomized the sample of children into low and high physical self-esteem scores, with the low group defined as those children scoring in the lower third of the group on the physical self-esteem scale of the Self-Perception Profile for Children. This strategy was adopted to assure that we created a high-risk group. Bivariate analyses indicated that the effect of the intervention was more pronounced for children who had low physical self-esteem at baseline than for those who had moderate to high self-esteem. **Figure 2** shows these results.

For the experimental group, mean adjustment scores for children with low physical self-esteem increased from 85.45 at T1 to 88.07 at T2; adjustment scores for children with high physical self-esteem increased from 90.30 at T1 to 91.65 at T2. For the control group, mean adjustment scores for children with low physical self-esteem decreased substantially from 86.67 to 81.24; scores for children with high physical self-esteem decreased from 90.79 to 89.98. No intervention effects were found for other self-esteem subscales.

As a way of summarizing main and interaction effects, we developed a multiple regression equation with T2 adjustment scores as the outcome variable, as given in **Table 3**. In step 1 the intervention group variable was entered and was marginally significant ($P < .10$). At step 2, when we controlled for baseline adjustment scores, the intervention effect increased ($P < .01$). Adding baseline physical self-esteem scores in step 3 slightly increased the intervention effect further. Finally, in step 4 the interaction between the intervention group and physical self-esteem (as a continuous measure) was added. These results suggest that the intervention was successful in improving adjustment for children in the intervention, especially if they had low physical self-esteem at baseline.

Overall, we found no evidence of any dose effects on the outcome of the intervention. During the intervention period, only 2 mothers in the control group called the veteran parents designated for this purpose. In the T2 interview, control group mothers were asked whether, in the past 12 months, there were times when it might have been useful to talk to someone who really understood what they were going through. More than 70% of the control group mothers answered in the affirmative, suggesting that a substantial number of mothers who have children with chronic illnesses are likely to feel the need to talk with other, more experienced mothers but are unlikely to initiate this contact over the telephone.

Table 1. Selected Diagnostic and Demographic Characteristic of Study Sample*

	Control Group	Experimental Group
Total No. of Participants	64 (100)	72 (100)
Maternal race/ethnicity		
White	31 (48)	37 (51)
African American	28 (44)	32 (44)
Hispanic	5 (8)	2 (3)
Other		1 (1)
Maternal welfare status		
No	57 (89)	65 (90)
Yes	7 (11)	7 (10)
Family composition		
Both biological parents	30 (47)	41 (57)
Mother alone	23 (36)	17 (24)
Other	7 (11)	13 (18)
Missing	4 (6)	1 (1)
Maternal educational level		
High school or less	15 (23)	31 (43)
Some college	26 (41)	15 (21)
College or higher	22 (34)	26 (36)
Missing	1 (2)	
Diagnosis of child's condition		
Diabetes mellitus	26 (41)	29 (40)
Sickle cell	11 (17)	14 (19)
Asthma	21 (33)	22 (31)
Cystic fibrosis	6 (9)	7 (10)
Child's health status		
Excellent	9 (14)	20 (28)
Very good	27 (42)	24 (33)
Good	15 (23)	15 (21)
Fair	8 (13)	11 (15)
Poor	4 (6)	2 (3)
Missing	1 (2)	
Symptom unpredictability		
No	11 (17)	7 (10)
Yes	53 (83)	65 (90)
Was the child ever so sick you thought he or she might die?		
No	31 (48)	40 (56)
Yes	33 (52)	32 (44)
Child age, y		
Range	7.2-10.8	7.2-11.5
Mean (SD)	9.09 (1.07)	8.99 (1.16)
Activity limitations in past year, d		
Range	0-365	0-365
Mean (SD)	24.41 (59.30)	22.04 (52.24)

*Data are given as the number (percentage) of participants unless otherwise stated.

COMMENT

This study demonstrates that our family support intervention had modest, positive effects on the adjustment of children with selected chronic illnesses. The intervention had a similar outcome for all diagnostic groups represented, suggesting that it could be effective for children with other long-term health conditions. The intervention may be especially relevant for the high-risk subgroup of children in this population who have low self-esteem. Condition-related variables such as symptom unpredictability or days of activity limitations were unrelated to the outcome measures.

Several features of this study enhance confidence in its results. First, the randomized trial design is a rigorous

Table 2. PARSIII Total and Subscales Scores by Intervention Group at Baseline (T1) and Postintervention (T2)*

	Control Group (n = 64)		Experimental Group (n = 72)	
	T1	T2	T1	T2
Total score	89.27 (10.00)	86.98 (11.23)	88.35 (9.91)	90.21 (9.27)
Hostility	22.47 (3.95)	22.00 (4.45)	22.22 (3.63)	23.23 (3.41)
Peer	12.21 (2.66)	11.53 (2.92)	12.00 (3.10)	12.22 (2.59)
Dependency	11.86 (2.14)	12.05 (2.00)	11.45 (2.56)	11.81 (2.59)
Withdrawal	14.76 (1.43)	14.80 (1.47)	15.01 (1.31)	14.95 (1.50)
Anxiety/depression	16.52 (2.26)	16.05 (2.48)	16.29 (2.52)	17.08 (2.14)
Productivity	11.24 (2.70)	10.33 (2.80)	11.03 (2.74)	10.78 (2.72)

*Data are given as the mean (SD) points. PARSIII indicates Personal Adjustment and Role Skills Scale III; T1, baseline score; and T2, 12-month later score. Due to rounding columns do not total.

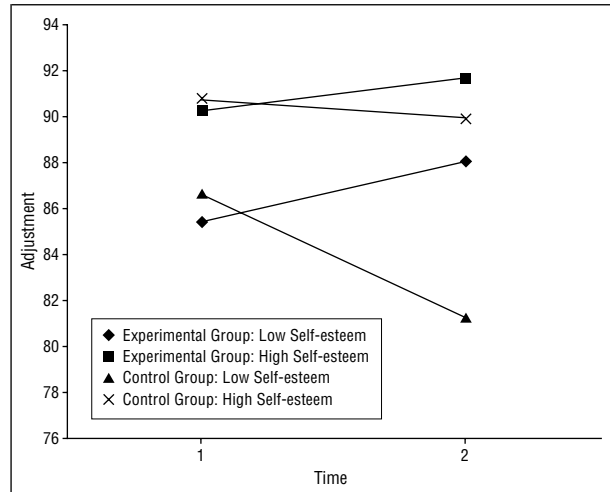


Figure 2. Interaction between intervention and physical self-esteem. Time 1 indicates distinct test times: 1, 45- to 90-minute interviews; 2, 12 months later. Adjustment was done during bivariate analysis.

Table 3. Standardized β Coefficients From Hierarchical Regression Predicting Postintervention Child Adjustment (Total PARSIII Scores)*

Variable	Step 1	Step 2	Step 3	Step 4
Intervention group	0.154†	0.191‡	0.207§	1.00‡
T1 adjustment scores		0.688§	0.626§	0.630§
T1 physical self-esteem scores			0.219§	0.373§
Intervention X T1 physical self-esteem scores				-0.812‡
R ²	0.02	0.49	0.53	0.55

*PARSIII indicates Personal Adjustment and Role Skills Scale III; T1, baseline scores for 134 participants. For an explanation of the various steps, see "Results" section.

† $P < .10$.

‡ $P < .01$.

§ $P < .001$.

method for program evaluation. Second, excluding those who refused randomization from an intent-to-treat analysis avoids potential dilution of program effects that could have resulted from inclusion of persons who were already functioning well, and for whom the intervention would have no additional benefit. Third, we randomized within recruitment site to avoid some potential site-specific biases. Fourth, the intervention was consistent with the structure of clinical subspecialty care (ie, it had a condition-

specific focus) while the evaluation design provided a sample size sufficient for reasonable statistical power.

Although these design elements support the credibility of our results, several notes of caution are important. First, the intervention did not have an effect on outcome variables measured through child report. This may have resulted from the fact that the children as a group reported high levels of emotional well-being. This is good news, but it increases the challenges of showing program effects.

Second, our sample may not be representative of the broader population of families of children with chronic health problems. Although we made an effort to recruit all potentially eligible families from the 16 clinics in Baltimore, selection bias may have affected our findings in unknown directions. Third, available resources precluded assessment of the mental health of fathers or of siblings, important dimensions for inclusion in future studies. Fourth, because many families received a low dose of the intervention, we may be underestimating the potential influence of this intervention.

As we noted earlier, we did not find a relationship between the amount of contact between the CLS-NM intervention team and participant outcomes. As we considered this issue, we realized that some families who were needy initiated a great deal of contact with the CLSs and the NMs. Hence, these families received a larger program dose. Other, equally needy families seemed to be withdrawn, did not initiate contacts, and hence, received a small dose. Both types of families, however, seemed to have benefited from the program. These observations led us to conclude that the relationship between dose and outcome is complicated by the level of baseline need, and that to assess this relationship adequately requires a measure of baseline need that is separate from the outcome measure. Further investigation of this issue should be undertaken in subsequent studies.

The actual numerical difference between the experimental and control group on the PARSIII, our measure of adjustment, was small, leading to concerns with clinical significance. However, over the course of the intervention the proportion of the control group children who fell into the maladjusted range increased, while the proportion of the experimental group children in the maladjusted range decreased. The proportion of children moving out of the maladjusted range is a good indicator of successful intervention.²⁷

Our results are consistent with findings from a conceptually similar intervention using family counselors that

What This Study Adds

Epidemiological and clinic-based studies indicate that children with chronic illnesses are at heightened risk for mental health problems. In this article we present child outcomes of a randomized, controlled clinical trial of a 15-month, community-based, family support intervention for children 7 to 11 years old with 1 of 4 chronic illnesses (diabetes mellitus, cystic fibrosis, sickle cell anemia, or moderate to severe asthma) and their mothers. Our intervention, involving CLSs in home and community settings, had a modest, positive effect on the adjustment of the children. The intervention had a similar outcome for all diagnostic groups, suggesting that it could be effective for children with other chronic illnesses. This intervention model offers a feasible method of extending the benefits of CLSs into the community and supports the idea that active outreach is an important part of a successful family support intervention.

was implemented in the early 1970s²⁸ and a more recent nursing intervention for children with a wide range of chronic illnesses.¹² The similar effects of the nursing intervention and our program may emerge from their similar outreach efforts and how the programs communicated reassurance and support to parents. In addition, more than 70% of our control group mothers said they would have found it useful to talk to a parent in a similar situation; however, they did not initiate a call to the experienced mother. This finding underscores the importance of outreach.

One of the novel aspects of this intervention involved the home-based and community-based work of the CLSs. To our knowledge, this is one of the very few programs that has aimed to bring the skill and expertise of child life into community settings. This intervention model offers a feasible method of extending the benefits of child life services beyond the hospitals, surgical departments, and outpatient clinics where CLSs are most likely to work.

Over the last decade, family support programs have become an accepted and important part of service systems for children with chronic health and mental health conditions, but the empirical foundation for these efforts is thin. Our study documents a workable approach to implementing a family support program and adds to the growing evidence that community-based, family centered care can make a difference.

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