Objective: To determine if participation in group sessions as part of health supervision visits for infants improves outcomes compared with individual visits in high-risk mothers.

Study design: Randomized controlled clinical trial.

Participants: Mothers of young infants who had at least 1 of the following risk factors: aged younger than 20 years at delivery, participation in Medicaid, less than a high school education, previous or ongoing substance abuse, or history of abuse as a child.

Setting: Two urban university pediatric clinics in Seattle, Wash.

Interventions: Mother-infant dyads were randomized to receive group well-child care (GWCC) or individual well-child care (IWCC) before the infant was 4 months old; the intervention continued until the child was 15 months old. Mothers completed the Sense of Competence and Social Isolation subscales from the Parenting Stress Index and Sarason’s Social Support Questionnaire at enrollment and again on completion of the study. During the 11-month study period, 7 health supervision visits were scheduled for each mother-infant dyad. Social workers met periodically with mothers during the study and assessed the following functional outcomes:

- return to school
- return to work
- enrollment in a substance abuse treatment program
- becoming pregnant

In addition, data on study children were collected from Child Protective Services to assess referrals because of suspected abuse and/or neglect.

Results: Data were collected on 213 mother-infant dyads, including 108 who received GWCC and 105 who received IWCC. At the conclusion of the study period, similar proportions of GWCC and IWCC mothers scored in the high-risk range on the Sense of Competence subscale, Social Isolation subscale, and the Social Support Questionnaire (P = .57, .32, and .59, respectively). For more than 50% of the mothers, scores on the Sense of Competence and Social Isolation subscales deteriorated during the study period from the not-high-risk range to the high-risk range, regardless of assignment to GWCC or IWCC. No differences were noted between GWCC and IWCC mothers for any functional outcome. During the study period, 8.8% of children receiving GWCC were referred to Child Protective Services vs 8.3% of those receiving IWCC (P = .85).

Conclusion: The format of well-child care may not be an important determinant of outcomes among high-risk mothers.

SUBJECTS AND METHODS

The study was conducted between March 1, 1993, and February 29, 1996. Mother-infant dyads were recruited for the study from 2 urban pediatric clinics at the University of Washington, Seattle; study interventions commenced when the infant was 4 months old and continued until the child reached the age of 15 months. Mothers recruited for the project had at least 1 of the following risk factors: single marital status, educational level lower than completion of high school, poverty (as defined by participation in Medicaid), aged younger than 20 years at delivery, previous or ongoing substance abuse, or history of abuse as a child. Mothers were excluded from the study if they were non-English speaking, or if their child had a serious ongoing medical condition.

Study procedures for the children, measurement of outcomes, and analyses of these outcomes have been previously described.12,13 At the time of enrollment, infants were randomized to receive either IWCC or GWCC. All care was provided by 1 of 2 nurse practitioners. Study health supervision visits were scheduled when the infants were 4, 5, 6, 8, 10, 12, and 15 months old. The timing of well-child care visits corresponded to the schedule used at our clinics for other programs for high-risk families. At each visit, for both IWCC and GWCC patients, the nurse practitioners followed a curriculum of topics for discussion that was developed prior to the beginning of the project. This curriculum was adapted from recommendations for health supervision published by the American Academy of Pediatrics.14 Individual well-child care visits followed the traditional one-to-one format; the nurse practitioners discussed specific questions dealing with child nutrition, safety, development, and behavior, followed by a physical examination. Mother-infant dyads randomized to GWCC were assigned to groups with other mothers and infants based on the age of the child; all of the infants in a particular group had birthdays within 2 months of one another. Each group stayed intact throughout the study period. At GWCC visits, the nurse practitioners facilitated a discussion of age-appropriate child-rearing issues with the mothers in the group. Every effort was put forth to make these sessions interactive, with encouragement of all of the mothers present to participate. Group sessions lasted 30 to 60 minutes; each child had a brief physical examination immediately prior to or after the session. Health screening and immunizations were provided to both IWCC and GWCC recipients.

At the time of enrollment, demographic data including age, ethnicity, marital status, educational level, and household income were collected for participating study mothers. In addition, the mothers completed a questionnaire assessing level of family stress, drug and alcohol abuse, and physical or sexual abuse or neglect as a child. Each of these measures has been previously validated.21,22

Both at enrollment and when their children concluded the project at the age of 15 months, study mothers completed the Sense of Competence and Social Isolation subscales of the Parenting Stress Index (PSI)20 and Sarason's Social Support Questionnaire (SSQ).23 The Sense of Competence subscale consists of 13 items and assesses all aspects of a child’s development, management skills, and confidence in handling the child. The Social Isolation subscale contains 6 items measuring social isolation from peers, relatives, and other emotional support systems. Normative data are available, and the scores correlate with parent-reported problems such as child abuse and later scores of the child’s development.19 The PSI has been used as part of pretesting and posttesting in the evaluation of parenting programs.24,25 as well as in studies on the relationship between parental stress and pediatric health care utilization.26 A score between 1 and 5 is possible for each item on the PSI; higher scores indicate more social isolation or lack of competence. For each subscale a score was calculated; scores higher than 17 on the Social Isolation subscale and higher than 36 on the Sense of Competence subscale were classified as “high risk” as defined by the developers of the instrument.20

Sarason’s SSQ is a 27-item questionnaire that inquires about the number of individuals who provide social support in a given situation, and the satisfaction with this support.20 For our study, mothers were considered to be at high risk for low social support if they reported an average number of 2 or fewer individuals who provided support, or if the average satisfaction with support was rated as “fairly satisfied” or less. In a previous sample at 1 of the study clinic sites, 40% of white mothers reported an average of 2 or fewer people providing support, and 20% were aged children, is an attractive alternative.9 In addition to allowing for greater discussion of developmental and behavioral issues,10,11 the group sessions might function as a support group for the mothers. Such support might include empathy from women dealing with similar issues, assistance with everyday activities such as child care, and the exchange of information about accessing services.

We conducted a 3-year randomized controlled trial comparing GWCC with traditional individual well-child care (IWCC) among high-risk urban families. Previously, we reported that children receiving GWCC and those receiving IWCC had similar developmental outcomes as well as similar health status and health-care utilization; there was a trend toward better mother-child interaction associated with GWCC.12,13 In this article we evaluate the outcomes in the mothers of study children in both groups. Prior to beginning the project, we postulated that mothers of children randomized to GWCC would report increased social support, increased feelings of competence as a parent, and better functional outcomes than mothers whose children were randomized to IWCC.

RESULTS

Of the 220 mother-infant dyads ultimately enrolled in the study, 111 were randomized to GWCC and 109 to IWCC. Seven mothers declined participation in the project after initially signing the informed consent; 3 of these had been randomized to GWCC and 4 to IWCC. Initial questionnaires were completed by 187 (88%) of the remaining 213 mothers. The results of the initial questionnaire are given in Table 1. The mothers had numerous signs of social disadvantage, including teenage pregnancy (24% of the study population), poverty (44.5% reported a
During the project, social workers met periodically with all enrolled mothers. In addition to assessing ongoing needs, helping with resource gathering, and providing supportive counseling, the social workers systematically collected information on maternal outcomes including return to work, return to school, enrollment in a substance abuse treatment program, and becoming pregnant. These data were obtained when the mother’s infant was between 5 and 9 months old, and again when the child was 10 to 15 months old. The social worker interviews were usually conducted at the time of the health supervision visits; some data were collected by telephone interview for mothers who were difficult to contact in person. Maternal outcome was categorized as positive if the mother responded affirmatively at either interview. If there was no positive response, and at least 1 negative response, to an outcome question, the outcome was classified as negative. If no response was collected at either interview for a particular question, the outcome was considered missing.

Names of participating children were reviewed by personnel from Washington State Child Protective Services (CPS) to determine if any referral had been made to that agency. Only children who had been referred to CPS during the period that they were enrolled in the project (from the ages of 4-15 months) were classified as positive for CPS referral. Infants who were referred to CPS prior to the age of 4 months were excluded from this analysis because the referral occurred before any study interventions.

In general, all mothers and infants who were enrolled in the project were eligible for outcome measurements regardless of how many study visits they had attended (ie, intention-to-treat analysis). Data from mothers who declined any participation in the project after initially signing the informed consent forms were excluded. In addition, maternal outcome measures, other than CPS data, were not obtained for mothers whose infants were removed from the home during the study.

Results of PSI and SSQ evaluations in mothers whose children received GWCC and those whose children received IWCC were compared in several ways. First, the proportion of mothers with scores in the high-risk range for social support, sense of competence, or social isolation among those in the IWCC or GWCC group were compared using \(\chi^2\) tests. For each mother who completed the PSI and SSQ at both the time of enrollment and at completion, there were 4 possible outcomes on each scale, as follows: a mother could have been classified as not high risk at both measurements; she could score in the high-risk range on both occasions; she could change from high risk to not high risk; or she could change from not high risk to high risk. The last possibility is obviously the worst possible outcome; the best demonstration of the effect of any intervention would be for a mother to start in the high-risk range, but test as not high risk at the end of the project. Differences in the percentages of IWCC or GWCC mothers in each category were assessed with \(\chi^2\) tests. The subscales of the PSI can also be used to generate continuous scores for sense of competence and social isolation. For each mother, the changes in these continuous scores from enrollment to completion were calculated. Regression analysis was used to assess the effect of randomization to GWCC or IWCC on these changes, after adjusting for the score at the time of enrollment. Prior to the beginning of the study, it was anticipated that 40% to 50% of mothers whose children received IWCC would score in the high-risk range on each of the PSI subscales and the SSQ at the end of the project. Based on these figures, to have a power of 80% to detect a difference of 25 percentage points in the proportions of GWCC and IWCC mothers classified as high risk, analyzable data were needed on each of these measures from 132 mothers.

\(\chi^2\) Tests were also used to compare the proportion of mothers in the GWCC and IWCC groups who returned to work, returned to school, entered a substance abuse treatment program, or became pregnant during the project. For the returned to school variable, data were analyzed only for mothers who were non–high school graduates at the time of delivery. Similarly, only women who had a positive result on screening for ethanol and/or other drug abuse on the initial questionnaire were included in the data analysis of the entered a substance abuse treatment program.

To assess the effect of GWCC or IWCC on CPS referral, \(\chi^2\) tests were used. For all statistical tests, differences were considered statistically significant when \(P<.05\).

The study was approved by the Institutional Review Board of Children’s Hospital and Medical Center, Seattle. Signed informed consent was obtained.
Study outcomes are also summarized in Table 2. The percentage of children receiving GWCC who were referred to CPS during the study period was 8.8% vs 8.3% of those receiving IWCC (P=.85). Six children (2 from the GWCC group and 4 from the IWCC group) were referred to CPS after completing the study. In addition, data on 6 infants (4, GWCC; 2, IWCC) who were referred to CPS prior to beginning the project were excluded from the analysis.

At the conclusion of the study, a high proportion of mothers completing the PSI scored in the high-risk range on both the Sense of Competence and the Social Isolation subscales. No significant differences were noted for either measure between mothers whose children received GWCC and those whose children received IWCC (P=.57 and .32, respectively). Since these measures were also administered at the time of enrollment, perhaps the best way to analyze the results is to compare changes in scores from enrollment to completion of the project. One hundred forty mothers completed the Sense of Competence subscale and 132 completed the Social Isolation subscale at both enrollment and completion of the study. Change in status on these subscales during the course of the project is given in Table 3. No significant difference in change in status was noted for mothers in the GWCC vs the IWCC group for the outcome of either measure. Overall, only 8.4% of mothers who completed the Sense of Competence subscale and 11.4% of those who completed the Social Isolation subscale showed definite improvement, demonstrated as a change in status from high risk at enrollment to not high risk at the conclusion of the study. Conversely, for 50.8% of mothers completing the Sense of Competence subscale and 56.4% completing the Social Isolation subscale at both times, scores deteriorated from the not-high-risk range to the high-risk range during the project. There were also no significant differences when these outcomes were analyzed as continuous variables. After controlling for scores at the beginning of the study, the change from enrollment to completion for the Sense of Competence and Social Isolation subscales was not associated with randomization to either GWCC or IWCC (P=.8 and .4, respectively).

At the completion of the study, 74.7% of mothers of GWCC children and 79.5% of mothers of IWCC children scored in the high-risk range for low social support (P=.59). As with the PSI subscales, there was no difference in change in status from enrollment to completion between GWCC and IWCC mothers (Table 3). Of the 145 mothers who completed the SSQ at both times, 8.3% progressed from high risk to not high risk for low social support during the study, while 17.2% went from not high risk to high risk.

Functional outcomes, as assessed at the social worker interviews, were similar in mothers whose children received GWCC and those whose children were IWCC recipients (Table 2). Of the 26 mothers who had a positive test result for ethanol or other drugs on the initial questionnaire and who completed a social worker interview, 6 (23%) enrolled in a substance abuse treatment program during the project; no difference was found between GWCC and IWCC mothers (P=.99). Fifty percent of mothers of GWCC children who were not high school graduates returned to school vs 36.8% of those whose children received IWCC (P=.55). During the study period, of all mothers of both groups, 38.6% either returned to work or found new employment, and 7.7% became pregnant. There was no difference between the GWCC and the IWCC groups for either of these outcomes (P=.35 and .98, respectively).

Detailed guidelines for the periodicity and content of well-child care visits have been developed as part of the Bright Futures program sponsored by the Maternal and Child Health Bureau and the Health Care Financing Administration.23 Payment for well-child care visits is provided by several publicly funded programs as well as by private insurers.24 The model of the one-to-one health supervision visit has been adopted with little evidence that it is the most effective format for providing well-child care. It is possible that other techniques for providing well-child care might maximize outcomes without increasing costs. The overall objective of our study was to rigorously evaluate an innovative method for providing

### Table 1. Characteristics of Study Mothers at the Time of Enrollment

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>GWCC (n = 94)</th>
<th>IWCC (n = 93)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>23.1</td>
<td>25.0</td>
</tr>
<tr>
<td>20-29</td>
<td>60.4</td>
<td>55.4</td>
</tr>
<tr>
<td>≥30</td>
<td>16.5</td>
<td>19.6</td>
</tr>
<tr>
<td>Education, grade level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td>15.1</td>
<td>10.0</td>
</tr>
<tr>
<td>10-11</td>
<td>22.6</td>
<td>18.9</td>
</tr>
<tr>
<td>12</td>
<td>26.9</td>
<td>34.4</td>
</tr>
<tr>
<td>&gt;12</td>
<td>35.5</td>
<td>36.7</td>
</tr>
<tr>
<td>Household income, dollars/mo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;500</td>
<td>46.3</td>
<td>42.7</td>
</tr>
<tr>
<td>500-999</td>
<td>34.1</td>
<td>35.4</td>
</tr>
<tr>
<td>≥1000</td>
<td>19.5</td>
<td>20.7</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>30.9</td>
<td>28.0</td>
</tr>
<tr>
<td>African American</td>
<td>42.5</td>
<td>44.1</td>
</tr>
<tr>
<td>Other</td>
<td>26.6</td>
<td>28.0</td>
</tr>
<tr>
<td>Single marital status</td>
<td>67.0</td>
<td>68.5</td>
</tr>
<tr>
<td>Positive screen test result</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For alcohol</td>
<td>11.8</td>
<td>3.2</td>
</tr>
<tr>
<td>For other drugs</td>
<td>20.7</td>
<td>8.8</td>
</tr>
<tr>
<td>For depression</td>
<td>33.0</td>
<td>43.0</td>
</tr>
<tr>
<td>Abused as a child</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physically</td>
<td>17.2</td>
<td>13.0</td>
</tr>
<tr>
<td>Neglected</td>
<td>19.6</td>
<td>10.9</td>
</tr>
<tr>
<td>Sexually</td>
<td>19.6</td>
<td>17.2</td>
</tr>
<tr>
<td>Difficult life circumstances</td>
<td>33.3</td>
<td>27.5</td>
</tr>
<tr>
<td>Low social support</td>
<td>69.1</td>
<td>60.2</td>
</tr>
<tr>
<td>Maternal high-risk assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For low sense of competence</td>
<td>10.6</td>
<td>12.0</td>
</tr>
<tr>
<td>For feelings of social isolation</td>
<td>28.7</td>
<td>26.1</td>
</tr>
</tbody>
</table>

*Values are expressed as percentage of study participants.
†Children of mothers were randomized to 1 of 2 groups. GWCC indicates group well-child care; IWCC, individual well-child care.

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health supervision for children in high-risk families. Although the most direct way to do this was to assess short-term outcomes in the children, it was important also to evaluate the effects of well-child care on the mothers. The potential positive benefits of GWCC sessions functioning as support groups for the mothers are somewhat nebulous. Telleen et al21 reported that mothers who attended either a twice-weekly informal support group or a weekly parenting education class, for 10 weeks each, had a greater decrease in social isolation and a greater increase in social support than a control group of mothers whose children received only routine medical care. Mothers who report more social support provide a more stimulating home environment for their children.7 In addition to emotional support, we had hoped that the group sessions would become a source of information on solving the problems of everyday life, leading to improved functional outcomes in the mothers. Unfortunately, in this study we failed to demonstrate that GWCC had any increased efficacy for high-risk mothers when compared with IWCC. Mothers whose children received GWCC had similar results on assessments of social support, social isolation, and a sense of competence as parents as those whose children received IWCC. There were also no differences between GWCC and IWCC mothers for any functional outcome such as return to work or school or enrollment in a substance-abuse treatment program.

Our results should be interpreted with caution; there are limitations to our study that tend to bias the results in favor of the null hypothesis. Because of our restrains on recruiting mother-infant dyads, the number of mothers in each cohort randomized to GWCC was suboptimal. In addition, while all mothers in a group were classified as high risk, the mothers in an individual GWCC cohort were frequently of dissimilar ages and backgrounds. Perhaps the biggest limitation to the study was the restriction that the number of mothers in each group was insufficient for meaningful comparisons.

### Table 2. Comparison of Study Outcomes Among Mothers Whose Children Received GWCC and Those Whose Children Received IWCC

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Total No. of Mothers Eligible</th>
<th>Total No. (%) of Mothers Who Completed Outcome Measure</th>
<th>Positive Outcome Rates (%)†</th>
<th>GWCC</th>
<th>IWCC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referred to CPS</td>
<td>207</td>
<td>164 (79)</td>
<td>7/80 (8.8)</td>
<td>7/84 (8.3)</td>
<td>.85</td>
<td></td>
</tr>
<tr>
<td>High-risk assessment‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sense of competence</td>
<td>210</td>
<td>141 (67)</td>
<td>41/72 (56.9)</td>
<td>35/89 (50.7)</td>
<td>.57</td>
<td></td>
</tr>
<tr>
<td>Social isolation</td>
<td>210</td>
<td>151 (72)</td>
<td>48/71 (67.6)</td>
<td>61/80 (76.3)</td>
<td>.32</td>
<td></td>
</tr>
<tr>
<td>Low social support</td>
<td>210</td>
<td>158 (75)</td>
<td>56/75 (74.7)</td>
<td>66/83 (79.5)</td>
<td>.59</td>
<td></td>
</tr>
<tr>
<td>Enrolled in treatment program</td>
<td>30</td>
<td>26 (87)</td>
<td>5/19 (26.3)</td>
<td>1/7 (14.3)</td>
<td>&gt;.99</td>
<td></td>
</tr>
<tr>
<td>Became pregnant</td>
<td>210</td>
<td>168 (80)</td>
<td>9/89 (10.1)</td>
<td>4/79 (5.1)</td>
<td>.35</td>
<td></td>
</tr>
<tr>
<td>Returned to school</td>
<td>59</td>
<td>47 (80)</td>
<td>14/28 (50.0)</td>
<td>7/19 (36.8)</td>
<td>.55</td>
<td></td>
</tr>
<tr>
<td>Returned to work</td>
<td>210</td>
<td>168 (80)</td>
<td>34/89 (38.2)</td>
<td>31/79 (39.2)</td>
<td>.98</td>
<td></td>
</tr>
</tbody>
</table>

‡Sense of Competence and Social Isolation were assessed with 2 subscales by those names from the Parenting Stress Index19; low social support was assessed by the Sarason’s Social Support Questionnaire.20

### Table 3. Assessments of Risk Status for Sense of Competence as Parent, Social Isolation, and Social Support of Mothers When Their Children Were Ages 4 and 15 Months

<table>
<thead>
<tr>
<th>Well-Child Care Study Group (No. of Mothers Who Completed Assessment at Both Times)*</th>
<th>Status Compared Between Children at Ages 4 mo/15mo†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Risk/ Not High Risk</td>
</tr>
<tr>
<td>Sense of Competence‡</td>
<td></td>
</tr>
<tr>
<td>GWCC (66)</td>
<td>6.1</td>
</tr>
<tr>
<td>IWCC (66)</td>
<td>10.6</td>
</tr>
<tr>
<td>Social Isolation‡</td>
<td></td>
</tr>
<tr>
<td>GWCC (75)</td>
<td>9.3</td>
</tr>
<tr>
<td>IWCC (65)</td>
<td>13.8</td>
</tr>
<tr>
<td>Social Support§</td>
<td></td>
</tr>
<tr>
<td>GWCC (76)</td>
<td>10.5</td>
</tr>
<tr>
<td>IWCC (69)</td>
<td>5.8</td>
</tr>
</tbody>
</table>

*GWCC indicates group randomized to group well-child care; IWCC, group randomized to individual well-child care.
†Mother-child dyads were randomly enrolled in either GWCC or IWCC programs at child’s age 4 months and completed the programs at child’s age 15 months.
‡Sense of Competence Subscale and Social Isolation subscale were extracted from the Parenting Stress Index.19
§Social support was measured by Sarason’s Social Support Questionnaire.20
the intensity of the intervention. Seven group sessions
were scheduled during an 11-month period for each
family randomized to GWCC, and compliance with sched-
uled study visits was 47%. Thus, the average mother whose
child received GWCC attended 3 to 4 sessions, each last-
ing 30 to 60 minutes, over 11 months. The results of the
study might have been different if the size of the indi-
vidual groups had been larger, the mothers in each group
more similar, and more group sessions had been at-
tended. Nevertheless, our experiences with the group ses-
sions may be typical for urban teaching clinics in which
new patients are assigned variously to residents, nurse
practitioners, or attending physicians to achieve educa-
tional goals.

An unexpected finding of the study was the dis-
couraging trend for mothers to feel less competent as
parents and more isolated socially when their children
were 15 months old compared with when the children
were 4 months old. For both the Sense of Competence
and Social Isolation subscales, more than 50% of moth-
ers progressed from not high risk to high risk during
the 11-month study period; this deterioration was unaf-
fected by randomization to either GWCC or IWCC.
Previously, Olson and DiBrigida25 reported that 42% of
mothers of children 12 to 24 months old had positive
test results on screenings for depression; this figure is
substantially higher than the 19% rate of positive results
on depression screens among mothers of children
whose ages spanned a wider range.15 These data indi-
cate that toddlerhood is a stressful time for mothers,
and suggest a reevaluation of when services to parents
might be most beneficial. Much of the current emphasis
of parenting programs and health supervision is on the
first few months of a child’s life23,26,27; perhaps it would
be more appropriate to concentrate some of these pro-
grams on the second year of life.

In retrospect, our hypothesis that group sessions
would substantially improve outcomes in high-risk moth-
ers may have been overly optimistic. However, results
among women whose children were randomized to
GWCC were no worse than for those whose children were
randomized to IWCC, and GWCC may have some ben-
efits for children.12 Thus, GWCC should be viewed as a
viable option for providing well-child care to high-risk
families.

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