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Caregiving demands and well-being in parents of children treated with outpatient or inpatient methotrexate infusion: A report from the Children's Oncology Group

Katherine Patterson Kelly, PhD RN¹, Diane Keegan Wells, MSN RN², Lu Chen, PhD³, Elaine Reeves, CCRA⁴, Ellen Mass, MSN RN⁵, Bruce Camitta, MD⁶, and Pamela S. Hinds, PhD RN FAAN¹

¹Children's National Medical Center, George Washington University, Washington, DC

²University of Maryland Medical Center, Baltimore, MD

³Children's Oncology Group, Arcadia, CA

⁴University of Oklahoma Health Sciences Center, Oklahoma City, OK

⁵Hackensack University Medical Center, Hackensack, NJ

⁶Midwest Children's Cancer Center, Milwaukee, WI

Abstract

Parent well-being is affected by their child's oncology treatment regimen and associated caregiving demand. Parental caregiving demands and well-being were evaluated in 161 parents from 47 sites whose child was randomized to receive either a 4-hour (outpatient) or 24-hour (inpatient) methotrexate infusion during consolidation treatment for acute lymphoblastic leukemia (ALL). A majority of patients randomized to the 4-hour infusion (66.3%) received the infusion as an inpatient. The most frequently reported reasons for this were lack of an adequate outpatient facility (53.6%) and physician preference (25.0%). There were no differences between care giving demand and well-being total scores by either randomized or actual infusion location with one exception: well-being scale fatigue scores were significantly greater ($p=0.001$) for parents whose child received the outpatient infusion. Mean total well-being scores for both the 24-hour arm ($\mu=42.6$; SD 16.2) and the 4-hour arm ($\mu=40.6$; SD 14.1) were elevated compared to healthy control populations. Additional research is needed to characterize impact of treatment setting on parental caregiving demand and well-being during their child's treatment for ALL. Investigators examining impact of treatment location in randomized clinical trials need to control for institutional variability in outpatient care delivery resources.

Correspondence: Katherine Patterson Kelly PhD RN, Children's National Medical Center, 111 Michigan Ave NW, Washington DC 20010, Fax: 202-476-3425, Phone: 202-476-2689, kakelly@childrensnational.org.
Reprints: Children's Oncology Group Operations Office, Publications Office, 440 E. Huntington Drive, 4th Floor, Arcadia, CA 91006-3776

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Keywords

caregiver; neoplasms; parents; children; clinical trials; caregiver burden

INTRODUCTION

A child's diagnosis of cancer immediately affects parents' roles and sense of well-being. Contributing factors include: the acute onset of the disease, the intense and demanding inpatient, outpatient and home-based treatments required, and the potential life-threat to the ill child. During their child's treatment, parents take on new, complex caregiving roles that include wideranging technical and emotional care beyond usual childcare responsibilities¹. The demand of providing care for a child with cancer negatively impacts parents' overall quality of life and role functions²⁻⁵.

Pediatric oncology treatment and care such as intravenous chemotherapy, antibiotics and parenteral nutrition - once only given to inpatients - are now delivered in outpatient and home settings. This transition towards clinic or home treatment places responsibility on parents for administering therapies and for monitoring the impact of those therapies on their child. The increasing parental caregiving demands can adversely affect the entire family system⁶.

The majority of children with acute lymphoblastic leukemia (ALL) in North America are treated on Children's Oncology Group (COG) protocols. Studying perceptions of parents whose children are enrolled on these protocols regarding parental time, effort, and caregiving demand for a child with ALL may help clinicians to identify high demand periods in a treatment protocol and to adequately prepare parents for these periods. Educational and supportive interventions could help families deal with caregiving demands and potentially minimize the negative impact of caregiving on the family. Also, methods to estimate caregiving demand could yield essential information for cooperative group intervention studies that involve outpatient delivery of cancer treatment. The aim of this study was to determine whether parent caregivers whose child received methotrexate as a 4-hour infusion (i.e. outpatient care) reported greater caregiving demand and lower family member well-being than did parents whose child received methotrexate as a 24-hour infusion (i.e. inpatient care).

MATERIALS AND METHODS

This prospective cohort study (ACCL01P3) was a companion study linked to two randomized Phase III treatment protocols (P 9904/P9905). Data were collected at week 13 corresponding to the 3rd of 6 "high dose" methotrexate infusions, a time of high treatment intensity when the randomized treatments of 4-hour (outpatient) versus 24-hour (inpatient) methotrexate infusions were administered. Parental caregiving for the outpatient administration could require tasks such as delivering intravenous therapy in the home, administering the rescue medication (leucovorin) and monitoring intake and urine output. Study procedures were pilot tested in 10 sites that participated in P9705, the pilot study for P9904/P9905. Nurses from each site confirmed feasibility of administering planned

measures and an overall assessment of increased parent caregiving demands in parents whose children received the 4-hr outpatient methotrexate infusion. Because a small number of sites indicated some concern with administering the 4-hr methotrexate infusion as an outpatient, plans to document reasons for this was incorporated into the study design.

Sample and setting

Parents or legal guardians who identified themselves as the primary caregiver for a child who was enrolled on either of the two studies were eligible for study participation. Sample size calculations were based on a two- group independent sample t-test comparing the total Care of My Child with Cancer (CMCC) demand score for the 4-hour vs. the 24-hour infusion groups. We identified a needed sample size of 142 (71 per group) to detect an effect size of 0.47 standard deviation (or 8.77 score difference based on a standard deviation of 18.5) in total demand assuming a two-sided alpha of 0.05 with 80% power. We targeted an accrual of 164 to account for projected attrition, missing data, and other reasons yielding non-evaluable participants. We over-accrued by 5% (n=172), yielding a final sample of 161 evaluable parent participants (defined as those with data from both CMCC and Family Member Well Being (FMWB) measures).

Procedure

A nurse at each of the participating COG institution served as the study site coordinator. The Clinical Research Associate (CRA) study team member contacted institutions that enrolled children on P9904 or P9905 to notify them of the study. To facilitate accrual and ensure timely data collection, the CRA tracked institutional IRB approval and enrollments, and reminded site personnel of data collection requirements⁷. Semi-annual study training sessions and follow-up meetings were held at COG meetings during the study.

After institutional IRB approval, eligible parents/legal guardians received verbal and written explanation of the study and reviewed the study questionnaires prior to giving consent. Study instruments were administered in a random sequence to reduce impact of respondent fatigue. Parent caregivers completed study measures during their child's clinic visit. The study site coordinator assisted the parent with data collection as necessary. All hard copies of study instruments were sent to a central site for quality review, scoring and data entry. Data entry followed standard procedures including double data entry to reduce likelihood of error. Copies of completed and scored instruments were then forwarded to the COG Research Data Center to be archived.

Instruments

The Care of My Child with Cancer (CMCC)⁸ is a 28-item scale that measures both the time required and the degree of effort or difficulty of certain care-giving tasks completed by family members in the previous week as part of the care given to their child with cancer. Items are listed under broad content domains. Initial factor analysis revealed two subscales, physical and emotional caregiving⁸. Item scores for time/effort range from 1 (no time or no effort – meaning the caregiving task was not completed by the parent) to 5 (more than 5 hours in the last week or a great deal of effort). Total demand for individual items is computed by taking the square root of the product of the raw time and effort scores. Total

time/effort/demand scores and those for subscales and domains are computed by taking the sum of the individual item time/effort/demand scores for the items involved. Higher scores indicate more time and effort for caretaking. Total scores range from 0 to 112. In several studies the CMCC demonstrated acceptable test-re-test ($r=0.90$), internal consistency (Cronbach's $\alpha=0.92-0.93$) and construct validity (increased demand associated with more intense treatment and poorer child and parent QOL)^{4, 8, 9}. The median completion time of the CMCC is 10 minutes. Internal consistency coefficients were acceptable in this sample. Cronbach's α for total parental caregiving time was 0.87, for effort (0.91), and for total demand (0.90). Coefficients for the emotional caregiving subscale were 0.85 for time, 0.89 for effort, and 0.88 for total emotional caregiving demand; coefficients for the physical caregiving subscale were 0.60 for time, 0.74 for effort, and 0.70 for total physical caregiving demand.

The Family Member Well-being Index (FMWB) is an 8-item, 11-point (0="not at all" to 10="Very much") numeric rating scale designed to measure a family member's estimate of his or her overall emotional, social, interactional and physical well-being during the previous week. Six items are reverse scored. Total score is obtained by summing the item scores. Higher scores reflect higher well-being. Completing the scale requires 2 to 4 minutes. The FMWB has demonstrated acceptable internal consistency (Cronbach's α of 0.85) and concurrent validity (moderate to strong positive correlations with measures of family coherence, resiliency, problem solving communication, and social support, and negative correlations with spouse emotional distress)¹⁰. In this sample, the internal consistency coefficient for the FMWB was 0.80.

Family demographic data included: age, gender, race/ethnicity, family structure (number of children living in household, parents' marital status), socioeconomic status (parental educational level, parent occupations, family income, type of housing), and access to healthcare insurance (if patient insured, primary payer, if employer contributed to insurance). The protocol also included a form used to document the reasons that a study participant who was randomized to receive methotrexate infusion as an outpatient instead was hospitalized for the infusion. The form included seven potential reasons that were identified by the clinicians on the study team. The study site coordinator completed this form after consultation with the patient's clinicians.

Analysis

All comparisons were performed by as-randomized analyses (4-hour infusion vs. 24-hour infusion) and then by as-treated analyses (in-patient vs. out-patient). Chi-square tests were used to compare patient/family demographics between groups. Two independent sample t-tests were used to compare the mean of CMCC/FMWB scores between groups. All p values were based on two-sided test and no multiple comparison adjustments to the p values were made. P value < 0.05 was considered statistically significant. For as-treated analyses, due to the imbalance in sample size and small number for out-patient group (28 vs. 133), the power for detecting the design effect size would have been 62%. Because the study was underpowered to determine differences in the as-treated analyses, we examined the findings

for trends (defined as $p \leq 0.10$) in differences between actual inpatient and outpatient parental caregiving demand.

RESULTS

Sample characteristics

The majority of participating patients were Caucasian ($n=131$; 81.37%); the majority of parents were married ($n=116$; 72.05%), reported annual household incomes of greater than \$35,000 ($n=82$; 50.93%) and had completed some college education (mothers $n=97$; 60.25%; fathers $n=72$; 44.72%). Among the 161 evaluable parent caregivers, 78 parents' children were randomized to the 24-hour methotrexate arm and 83 to the 4-hour infusion. A large number of the children (55 of 83, 66.3%) randomized to the 4-hour infusion actually received the infusion as an inpatient (Figure 1) with only 28 children receiving their 4-hour infusion as an outpatient (Figure 1). The most frequently reported reasons that patients randomized to the 4-hour infusion received the infusion as an inpatient were lack of an outpatient facility that accommodated extended hours (53.6%) and physician preference (25.0%) (Table 1). Caregivers did not differ significantly between the two arms except that mothers of children who received the infusion as an outpatient had higher education level (more than 12 years education; $p=0.01$). There were no statistically significant differences in each arm by child age, gender or race (Table 2).

Differences in parental caregiving demand and well-being between inpatient and outpatient methotrexate regimens

There were no differences in physical, emotional or total CMCC scores based on randomized infusion location or actual location. (Table 3) Likewise, there were no differences in total FMWB scores based on randomized or actual location of infusion. FMWB fatigue scores (How much energy, pep or vitality have you felt in the past week? rated 0=no energy at all/LISTLESS to 10= very energetic/DYNAMIC) were significantly worse for parent caregivers whose child received the methotrexate infusion as an outpatient as compared to parent caregivers whose child received infusion as inpatient ($p=0.001$). This was true for both randomized and actual place of treatment.

Though not reaching statistical significance, CMCC total, physical and emotional subscale mean scores were higher for parents in the actual outpatient group indicating greater parental caregiving demand. Likewise, the total FMWB mean scores were lower in the actual outpatient group indicating lower parental well-being. We examined the findings for trends ($p > 0.05$ but ≤ 0.10) that differentiated the actual inpatient and outpatient groups. Selected CMCC items (data not shown) revealed non-significant increases in effort ($p=0.10$) and total demand ($p=0.08$) for preparing and delivering intravenous medications. The amount of time providing emotional support to other children in the family was higher for parents whose children received methotrexate as an outpatient ($p=0.10$). There were no differences (i.e., $p > 0.10$) for administering oral medications, managing side effects, emotional support of the child with cancer and reporting symptoms to the treatment team. There was non-significant greater sadness ($p=0.08$) reported by parents in the outpatient group.

Feasibility of companion trials in the cooperative group setting

ACCLo1P3 accrual was completed in 25 months (January 2003-February 2005), and accrued 172 participants with 161 evaluable participants. Accrual was brisk despite a 3-month closure of the two treatment protocols to which this study was linked thereby suspending accrual to this protocol during the same timeframe. The participants were enrolled from 47 former Pediatric Oncology Group sites in the US and Canada. Data collection imposed a minimally increased workload on the participating sites. Of the 161 evaluable participants, 156 completed all the items for CMCC and 159 completed all the items for FMWB. Missing data were minimal and less than reported in a psychometric evaluation of the CMCC using a national survey of parents⁹. A network of RN study site coordinators assumed responsibility to implement the trial, further demonstrating the feasibility of implementing companion trials designed to answer targeted questions regarding impact of protocol treatment on family caregivers.

DISCUSSION

This study was designed to assess whether moving complex chemotherapy regimens into the outpatient setting would increase parent caregiving demands and/or decrease their well-being. We hypothesized that children randomized to the 4-hour methotrexate infusion would receive the infusion in an outpatient setting but did not specify this for study inclusion. We confirmed the feasibility of the planned protocol aims/hypotheses through pilot testing in institutions participating in the P9904/P9905 pilot study and the standard cooperative group processes including votes taken at various disease and discipline meetings to indicate agreement with protocol plans during the concept development phase and scientific review of the final concept at both the cooperative group and National Cancer Institute levels. In addition we polled members of the Nursing Discipline regarding how many institutions might not administer the 4- hour infusion as an outpatient. A minority of members present at two consecutive cooperative group meetings indicated that their institution would not administer the 4- hour infusion as an outpatient. From these members we identified the potential reasons for not administering the 4- hour infusion as an outpatient to document these reasons in the study. We therefore did not anticipate a significant impact on the protocol design. Despite these efforts, the majority of participating institutions could not or chose not to give the 4-hour methotrexate infusion as an outpatient as originally expected, thus impacting our ability to answer the primary research question.

Even with these challenges, our results are informative. The primary reasons for giving the 4-hour methotrexate infusion in the inpatient setting included lack of adequate outpatient extended clinical infusion hours to deliver the required protocol treatments and clinician preferences for overseeing methotrexate delivery in the inpatient setting. Documenting the reasons medical care providers find it difficult to offer complex chemotherapy regimens in the outpatient setting will be useful for future clinical trial planning and/or developing outpatient chemotherapy service programs. These reasons represent latent variables that must be considered when planning and monitoring randomized clinical trials involving differing chemotherapy delivery settings.

Mean total CMCC scores were similar for parents in both the 24- hour ($\mu=64$; SD 17.4) and 4- hour randomized infusion arms ($\mu= 65.2$; SD 14.7). Because we only had 28 caregivers who actually provided care for the child as an outpatient, the study was underpowered to demonstrate differences in caregiving demand or family well-being between the two caregiver groups. The observed effect size in CMCC total scores was smaller compared to the target effect size, indicating the effect of treatment setting differences was smaller than anticipated. A similar finding of no differences in caregiving strain for parents by treatment setting was reported in another small study ¹¹.

Mean total FMWB scores were similar for parents in both randomized and actual treatment arms. When compared to FMWB in normative family samples, parents of children with ALL scored within the 30–45 percentile, indicating low family well-being ¹⁰. Caregivers reported significantly higher fatigue when their child was treated as an outpatient as compared to inpatient. Recent reports identified increased fatigue in parents of children with cancer^{3, 13} and an association between parents' perceptions of their child's symptom burden and their own emotional distress¹⁴. Future research must target the impact of increasingly complex chemotherapy regimens on caregiver fatigue and distress and caregiver ability to adhere to home and outpatient treatment regimens. While our findings provide additional evidence for the impact that caring for a child with cancer has on a family member's overall well being or quality of life³, additional research is needed to characterize parental risk for increased caregiving demand and reduced well-being during their child's treatment for ALL and other childhood cancers.

A single demographic variable was associated with treatment as an outpatient – the mother's educational level. We believe this demographic variable likely related to the clinician's assessment of the parent's ability to coordinate the complex medication administration regimen required to safely monitor a child after methotrexate infusion. The caregiving tasks included administering intravenous fluids and rescue medications on a strictly timed schedule, and monitoring intake and urine output. Hollingshead uses education level as a key variable to classify socioeconomic status¹². Therefore, the mother's educational level might also relate to the added financial resources available to these mothers to be in the home to provide care, to provide help with caring for other children in the home or the means to cover potential added costs related to the outpatient regimen.

Despite our inability to detect statistically significant differences between the two groups, our findings revealed important trends that merit consideration for future study. All mean scores for caregiving time, effort and demand including emotional and physical subscale scores were higher for the actual outpatient group. Borderline non-significant differences were found for the time caregivers spent providing emotional care in the outpatient as compared to the inpatient care setting. Parents who administer complex regimens at home do not have the support of additional hospital staff such as child life activity therapists or other mental health professionals to help address the child's emotional needs. On selected CMCC items, outpatient caregivers reported non-significantly increased effort and total demand administering parenteral medications. Additionally, a non-significant increase in time and total demand for providing emotional care for other children in the family was seen in parents whose child received the 4-hr methotrexate infusion as an outpatient. Parents

whose child received either the 4-hr or 24-hr methotrexate infusion as an inpatient often room in with the hospitalized child and might rely on other family members to provide emotional support for the other children in the family while the child was hospitalized. When the complex treatment was administered in the home, parent caregivers had to divide their attention amongst all family members without the same level of support by other professional and family caregivers as compared to when they accompanied their ill child for an inpatient hospital stay.

The cooperative group setting provided an excellent platform upon which to implement a supportive care study such as this one linked to clinical randomization of participants. Parents and other caregivers, who were already engaged in a clinical trial system of care delivery, were willing and able to report the demands of providing care to their child receiving cancer therapies. Clinical nursing staff and clinical research associates were enthusiastic in supporting this trial and were engaged in the identification of subjects and completing data collection procedures yielding a minimal missing data rate. A model system to provide clinical staff education pre-trial and ongoing throughout data collection was established in addition to a systematic method to trigger communication with site personnel when a potential participant enrolled on the companion clinical trial⁷. It will be important to document the relative efficacy of embedding these types of study aims directly onto disease-directed clinical trials as compared to our approach of developing a companion study to be implemented by institutions that choose to participate.

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Figure 1.
Consort diagram

Table 1

Reasons for hospitalization among patients randomized to 4-hr infusion Patients

Reasons for Hospitalization	Frequency (%)
Lack of an Outpatient Facility	27 (49.1%)
Physician preference	13 (23.6%)
Family preference/not able	7 (12.7%)
Institution policy/preference	5 (9.1%)
Other/unknown	3 (5.5%)

Table 2

Participant characteristics by actual place of treatment

	In-patient N=133	Out-patient N=28	P value
Patient Gender			0.35
Male	63 (47%)	16 (57%)	
Female	70 (53%)	12 (43%)	
Patient Race			0.21
White	111 (84%)	20 (74%)	
Non-White	21 (16%)	7 (26%)	
Unknown	1	1	
Patient Age			0.73
< 5	76 (57%)	15 (54%)	
>=5	57 (43%)	13 (46%)	
Caregiver Marital Status			
Married	94 (71%)	22 (79%)	0.68
Windowed	1 (0.8%)	0 (0%)	
Divorced	11 (8.3%)	3 (11%)	
Separated	2 (1.5%)	1 (3.6%)	
Never married	22 (17%)	2 (7.1%)	
Other	3 (2.3%)	0 (0%)	
Patient Type of Residence			0.73
Apartment/duplex/multiplex	17 (13%)	4 (14%)	
Condo/townhouse	9 (6.8%)	0 (0%)	
Detached/semi-detached house	81 (61%)	17 (61%)	
Trailer/Mobile home	12 (9.0%)	4 (14%)	
Other	13 (9.8%)	3 (11%)	
Don't know	1 (0.8%)	0 (0%)	
Annual Household Income			0.12
< \$10,000	13 (10%)	3 (11%)	
\$10,000–19,999	15 (12%)	2 (7.4%)	
\$20,000–34,999	22 (17%)	9 (33%)	
\$35,000–59,999	33 (25%)	1 (3.7%)	
\$60,000 or more	38(29%)	10 (37%)	
Refuse to answer	9 (6.9%)	2 (7.4%)	
Unknown	3	1	
Mother's Education			0.01
Less than college	57 (44%)	5 (18%)	
Some college	74 (56%)	23 (82%)	
Unknown	2	0	

	In-patient N=133	Out-patient N=28	P value
Father's Education			0.82
Less than college	65 (52%)	13 (50%)	
Some college	59 (48%)	13 (50%)	
Unknown	9	2	

* Comparison based on completed responses

Parental caregiving demand and family member well-being differences between randomized infusion status and by actual place of infusion

Table 3

Variable	Mean by Randomized Infusion Status (S.D.)			Mean by Actual Place of Infusion (S.D.)		
	MTX 24 hr	MTX 4hr	<i>P value</i>	Inpatient	Outpatient	<i>P value</i>
CMCC*						
Total Caregiving Time	68.6 (16.8)	69.7 (15.0)	0.68	68.3 (16.2)	73.5 (13.5)	0.12
Total Caregiving Effort	61.2 (19.2)	63.1 (15.9)	0.49	61.5 (17.8)	65.3 (16.2)	0.31
Total Caregiving Demand	64.0 (17.4)	65.2 (14.7)	0.65	64.0 (16.4)	67.6 (14.0)	0.30
Physical Caregiving Subscale (7 items)						
Time	17.0 (5.3)	16.6 (3.8)	0.58	16.7 (4.7)	17.3 (4.0)	0.56
Effort	14.8 (5.5)	14.5 (4.1)	0.74	14.5 (4.9)	15.3 (4.5)	0.45
Demand	15.6 (5.2)	15.4 (3.8)	0.69	15.4 (4.6)	16.1 (4.2)	0.45
Emotional Caregiving Subscale (13 items)						
Time	36.9 (9.8)	37.7 (9.7)	0.59	36.7 (9.9)	40.0 (8.8)	0.12
Effort	33.5 (11.7)	34.0 (10.3)	0.76	33.6 (11.1)	34.7 (10.4)	0.62
Demand	34.5 (10.0)	35.1 (9.5)	0.67	34.5 (9.9)	36.2 (9.0)	0.42
Physical care domain (13 items)						
Time	27.7 (8.0)	28.0 (5.5)	0.84	27.5 (7.0)	29.4 (5.5)	0.18
Effort	24.6 (8.3)	24.9 (5.8)	0.76	24.5 (7.3)	26.1 (6.1)	0.27
Demand	25.8 (7.9)	26.1 (5.4)	0.77	25.6 (6.9)	27.5 (5.6)	0.20
Emotional care domain (7 items)						
Time	20.3 (5.8)	21.0 (6.3)	0.49	20.3 (6.0)	22.5 (5.9)	0.09
Effort	18.4 (6.8)	19.1 (6.5)	0.53	18.6 (6.6)	19.7 (6.8)	0.41
Demand	18.9 (5.9)	19.7 (6.1)	0.43	19.1 (6.0)	20.6 (6.0)	0.22
Finances domain (1 item)						
Time	2.9 (1.3)	2.8 (1.3)	0.52	2.8 (1.3)	3.0 (1.3)	0.44
Effort	2.9 (1.4)	2.9 (1.4)	0.88	2.9 (1.4)	3.0 (1.4)	0.78

	Mean by Randomized Infusion Status (S.D.)	Mean by Actual Place of Infusion (S.D.)	
Demand	2.9 (1.3)	2.8 (1.3)	0.57
Family/Interpersonal Relationships domain (4 items)			
Time	9.6 (3.2)	10.3 (3.4)	0.15
Effort	8.9 (3.5)	9.9 (3.9)	0.09
Demand	9.1 (3.2)	10.0 (3.5)	0.09
Communication domain (3 items)			
Time	7.7 (2.6)	7.7 (2.8)	0.90
Effort	6.8 (3.0)	6.3 (2.4)	0.21
Demand	7.1 (2.6)	6.8 (2.3)	0.46
FMWB [#]			
Not worried about health	6.3 (3.3)	6.5 (3.3)	0.78
Relaxed	3.6 (3.1)	3.5 (2.6)	0.70
Energetic	5.4 (2.5)	4.2 (2.0)	0.001
Cheerful	5.3 (2.7)	4.9 (1.9)	0.22
Not afraid	5.8 (3.2)	5.8 (3.3)	0.98
Not angry	6.7 (2.8)	6.0 (3.0)	0.12
Not sad	5.2 (2.9)	5.7 (3.0)	0.23
Not concerned about another family member	4.3 (3.7)	4.0 (3.1)	0.55
Total FMWB	42.6 (16.2)	40.6 (14.1)	0.39

* CMCC: Higher scores = more time & effort & greater demand

[#] FMWB: Higher scores = greater well being