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# Behavioral Parenting Skills as a Novel Target for Improving Medication Adherence in Young Children: Feasibility and Acceptability of the *CareMeds* Intervention

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## Abstract

In pediatric cancer care, medication non-adherence is a significant driver of avoidable suffering and death. There is a lack of interventions designed for families of young children, where patient medication refusal/avoidance is a common barrier to adherence. We developed the *CareMeds* intervention which focuses on caregiver skills training to help young children take medicine calmly and without use of restraint techniques. The goal of this preliminary study was to assess the acceptability and feasibility of the *CareMeds* intervention. Caregivers of pediatric cancer patients (ages 2–10) whose children were on a home-based oral medication regimen were recruited to participate. Feasibility was examined through study enrollment and retention rates as well as reasons for refusal and drop out. Acceptability was evaluated through usability of and engagement with intervention components and an acceptability questionnaire. *Feasibility:* We recruited N = 9 caregivers to participate in this intervention pilot study and had a 75% enrollment rate. Reasons for declining included scheduling concerns ($n = 2$) and lack of interest ($n = 1$). The participant retention rate was 100% with 100% adherence to intervention sessions. *Acceptability:* Parents rated the sessions and resource materials as acceptable and reported frequent use of skills taught in the intervention. The *CareMeds* intervention is an acceptable and feasible strategy for caregivers of pediatric cancer patients and warrants future research to examine the efficacy of behavioral parenting skills interventions to improve medication adherence in young children.

### Keywords

Psychosocial; outcomes research; behavioral studies; pediatric oncology; adherence

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## Introduction

In the United States 50–88% of children do not take medication as prescribed.[1] Medication non-adherence can lead to worsening illness, avoidable and/or recurrent hospital admissions, increased health care cost, morbidity, and mortality.[2–4] Pediatric cancer is the number one cause of death by disease in children.[5] Yet, over 40% of patients have clinically significant non-adherence to medical treatments.[6] For the most common pediatric cancer, Acute Lymphoblastic Leukemia (ALL), children who miss just 10% of chemotherapy have a nearly 4-fold risk of cancer relapse.[7]

Administering daily medication to young children can be a difficult and stressful aspect of cancer caregiving.[8] Caregivers must learn how to coax resistant children to swallow bitter medicine, manage medication-related tantrums, and develop strategies to overcome child medication resistance.[6,9–12] Some treatment protocols require this be done every day for years. Research also documents that the medication-related education that doctors and nurses provide to these families can be variable, and predominantly focused on dosing schedules and medication related side effects.[13] Pediatric clinical care offers little parenting-related support to teach parents how to get young children to take medicine calmly and without use of restraint techniques.

Within the factors that shape medication adherence in young children, evidence is converging on behavioral parenting skills as promising targets for intervention. A large body of evidence supports the efficacy of behavioral parenting interventions (for a meta-analysis see Sanders et al.[14]). Evidence-based behavioral parenting interventions focus on increasing parents' knowledge, skills and confidence,[14,15] and have been effective in improving child health outcomes such as child weight management.[15–17] Behavioral parenting training includes a toolbox of practical skills and resources, such as effective strategies for praising, encouraging, and supporting children as they learn new skills. Training in behavioral parenting skills has been successfully implemented within pediatric clinical contexts. For example, an intervention that trained pediatric residents in positive parenting techniques improved residents' parenting consultation skills, which in turn improved parents' disciplinary skills.[18] To our knowledge, existing behavioral parenting skills interventions have not focused on enhancing medication adherence among pediatric cancer patients.

Building upon this research we developed the *CareMeds* intervention, which is a caregiver skills training intervention to reduce child medication refusal and avoidance. Sessions in the preliminary *CareMeds* intervention are designed to increase caregiver knowledge of strategies to reduce difficult child behavior related to medication administration. Behavioral parenting skills targeted are based upon Barber's model[19] of dimensions of parenting young children: support, psychological control, and behavioral control. Given the many demands placed on families coping with pediatric cancer as well as the considerable resources involved in implementing a new intervention, it is critical to assess feasibility of intervention recruitment and implementation before initiating a larger trial.[20] This study sought to explore the feasibility and acceptability of the 4-week *CareMeds* intervention to support

a future full scale randomized control trial.[21] We hypothesized that participants would meet a priori benchmarks for feasibility (≥75% enrollment, ≥80% of participants complete all study procedures) and acceptability (mean score ≥8 on acceptability questionnaire items; mean score of ≥3.5 on use of skills taught in intervention).[20]

## Methods

### Design

We recruited parents/caregivers of pediatric cancer patients (ages 2–10) whose children were on a home-based oral medication regimen at Roswell Park Comprehensive Cancer Center in Buffalo New York, USA. We examined feasibility through study enrollment and retention rates as well as reasons for refusal and drop out. We examined intervention acceptability through usability of and engagement with intervention components and participant satisfaction. The study was approved and overseen by the Roswell Park Comprehensive Cancer Center Institutional Review Board. The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Procedure

Participant recruitment began in November 2019 and continued through August 2020. Patient records were used to identify and approach eligible caregivers for recruitment. Eligibility criteria were: (1) being a caregiver of a child diagnosed with cancer; (2) child age between 2 to 10 years old; (3) child on treatment that includes home-based oral medication; and (4) verbal English fluency. We asked each family to identify the caregiver with primary medication responsibility. To replicate procedures that will be used in a larger trial, participants completed REDCap surveys pre- and post-intervention to capture sociodemographic characteristics, child disease characteristics, medication knowledge, medication burden, stress, and parenting behaviors.

**Intervention delivery.—**The *CareMeds* intervention consists of four weekly one-on-one coaching sessions delivered either in person or by phone, designed to last approximately 30 minutes. Participants were contacted by research staff following study enrollment to set up their first parenting skills session. The dates and times of sessions 2, 3, and 4 were confirmed upon the completion of the previous session. Research staff contacted caregivers with an appointment reminder the day before each scheduled session. Initially coaching sessions were conducted in-person, however amid the COVID-19 pandemic we needed to change this procedure and all coaching sessions were switched to phone conference. Across all sessions, 31% were held in person and 69% were conducted remotely. All coaching sessions were led by one Certified Child Life Specialist from the Roswell Park pediatric clinic. The Certified Child Life Specialist received 10 hours of training on intervention delivery that included an overview of the *CareMeds* intervention, manual, and scripts. The training included presentations, interactive discussions, and observed practice leading coaching sessions. Coaching sessions were guided by a structured intervention manual. Participants were given an intervention manual to take home which included additional resources for practice and review.

The *CareMeds* intervention (see Table 1) consists of three integrated components: (1) creating consistent medication routines, (2) education in child management strategies, and (3) training in specific parental behavioral techniques such as modeling, behavioral contingencies, and reinforcement.[15] One-on-one coaching sessions include behavioral practice and rehearsal, goal setting, action planning, and instructions on how to perform behaviors.[22]

## Measures

**Sociodemographic measures.—**After completing the informed consent process parents were asked to complete a short survey in REDCap. We used items replicated from the National Cancer Institute's Health Information National Trends Survey to measure self-reported caregiver gender, age, race, ethnicity, employment status, marital status, and household income.

**Child disease characteristics.—**We conducted medical record reviews to capture objective measures of the child's diagnosis, gender, child's current age, age at diagnosis, cancer treatment plan, list of prescribed medications, and time since diagnosis. Data abstraction was guided by a standardized form.

**Intervention feasibility.—**Study enrollment and retention data were captured through a standardized form completed by study research coordinators for each participant approached for study participation. The form captured each family invited to participate, and the reason(s) for declining if the caregiver declined participation. If the caregiver agreed to participate, the form included projected dates of study milestones, dates of actual completion of study milestones, and reasons provided by participant for any study delays or missing data. The interventionist completed a checklist after each parenting session to capture intervention fidelity data that recorded the topics covered in each session, length of session, and format of session (in-person, phone).

**Medication-taking barriers and use of behavioral parenting skills.—**In the beginning of the first intervention session caregivers were asked to complete a worksheet to describe their experiences with common barriers to medication taking. The barrier questionnaire was developed based upon our previous research[23–25] and common parenting-related barriers for adherence identified in the literature[6,9–12] including child avoidant behaviors, medication schedules/forgetting, unclear medication instructions, and ensuring medication supply and refills. Participants completed a worksheet at the end of the intervention sessions to report on their use of specific behavioral parenting skills using a 5-point Likert scale where 1 = never and 5 = always: positive attention, specific praise, avoiding negative talk, effective instruction, active involvement, acknowledging emotions, and sharing duties.

**Intervention acceptability.—**After intervention completion, participants completed a feedback survey that was administered though REDCap. The survey used a 10-point Likert scale where 1 = Not at all and 10 = Extremely to assess overall intervention satisfaction (*Overall, how enjoyable were the parent sessions? How helpful were the sessions?*) and

satisfaction with specific intervention components (*How helpful were the tips and strategies for improving your child's medication use? How useful were the resource materials?*).

## Data Analysis

Descriptive statistics were used to analyze quantitative data on study enrollment rates, reasons for refusal, retention rates, reasons for study drop out, usability of and engagement with intervention components and participant satisfaction. Qualitative data, including responses to open-ended questions about the program and feedback provided by participants during each parent session, were coded for themes using Microsoft Excel and illustrative quotes are presented.

## Results

### Participant characteristics

We were able to achieve the target sample size for this pilot study which was 9 families. All 9 caregiver participants were female, and the mean age was 39 years old (range 31–52 years). Eight participants described themselves as non-Hispanic and one identified as Hispanic. Eight participants self-described as white and one as Asian. Three participants had a high school diploma, two held an Associate's degree, and four held Master's degrees. Four participants were working full time, one was working part time, one was a full-time student, and three were not in the paid labor force. Six participants described their household structure as two-parent, and three were single/lone parents. One participant reported an annual household income less than $10,000, three had a total household income between $50,000 and $74,999 and five reported a total household income greater than $75,000.

The average age of participants' children was 6.6 years (range: 4–10 years). All but one of the children ($n$ = 8) were male. Children were diagnosed with a variety of pediatric cancers, including solid tumors, lymphoma, and cancers of the blood and bone marrow. At baseline, the median number of months since the children had been diagnosed with cancer was 13 (range: 3.5–53.5 months). Parents reported that their children took their oral medication in either liquid ($n$ =3), swallowed tablet ($n$ = 5), or chewable tablet ($n$ = 1) form.

### Caregiver-reported barriers to medication adherence

At baseline the most prevalent medication barrier reported was child avoidant behaviors, with 7 of 9 participants reporting this barrier (Table 2). Six participants reported unclear medication instructions as a barrier. Three participants reported medication schedules or forgetting as a barrier, and 1 participant reported difficulty ensuring adequate medication supply and medication refills.

### Intervention feasibility

Of the 12 eligible caregivers contacted about participating in the study, 9 agreed to participate and 3 declined, for a 75% enrollment rate. Among those who declined to participate, reasons cited were work schedule/not available for parent sessions ($n$ = 2) and lack of interest ($n$ = 1). The participant retention rate was 100% with 100% adherence

to intervention sessions. Participants demonstrated good adherence to the overall study schedule. For example, the number of days between Sessions 1 and 2 ranged from 6–9 days for all except one participant whose Session 1 and 2 were 23 days apart due to scheduling difficulty. Expected total time on study was 11–13 weeks; actual time on study ranged from 12–16 weeks. The average duration of the sessions was 42 minutes (range: 25–60 minutes). Across all parent sessions, 8% were rescheduled by parents.

### Intervention acceptability

Most participants rated the sessions and resource materials as acceptable, with mean ratings ranging from 8.75 to 9.75 on a 10-point scale. For overall acceptability of the intervention, participants reported that the sessions were enjoyable (mean 9.38, range 8–10) and helpful (mean 9.75, range 9–10). Participants reported that the tips and strategies for improving the child's medication use were helpful (mean 9.75, range 9–10) and that the resource materials were useful (mean 8.75, range 6–10). Participants reported frequent use of specific parenting skills taught in the intervention, with most participants reporting that they often or always applied positive attention, specific praise, avoiding negative talk, effective instructions, actively involving the child, acknowledging emotions, and sharing duties (Table 3).

In open-ended responses describing experiences applying intervention content during medication administration participants reflected on the helpfulness of skills taught in the *CareMeds* intervention. For example, reflecting on positive attention one participant stated: *I have been making more of a conscious effort to communicate with [child]. I will sit [child] on my lap and look into [child's] eyes. Then we take turns talking with one another.* One participant reflected on actively involving the child in medication routines: *[Child] is very involved and will even remind me that it is medicine time.* When asked about avoiding negative behaviors another participant stated: *I have been trying to decrease yelling and work on being calm. I can see [child] being more calm and less argumentative when I am calm.* Another participant reflected: *I have been taking deep breaths and trying not to give attention when he is misbehaving. I will walk away and collect myself if needed.* Finally, related to specific praise one participant shared: *[Child] has been repeating specific praise to himself after I say it. For example, I will say 'You did a great job holding still for that port access.' And [the child] will say 'I did do a great job holding still!'* Similarly, several participants reflected on the helpfulness of skills taught in the intervention for other aspects of cancer caregiving, including port accesses, treatment procedures, and wound care.

## Discussion

In pediatric cancer care non-adherence to medications is a significant driver of avoidable suffering and death. Many pediatric adherence interventions have been designed for and tested in families of adolescent and young adult patients (for reviews see [26–28]), and few explicitly target families of young children. Previous interventions to enhance pediatric medication adherence have focused on medication tracking/reminder systems (pill organizers, calendars, medication reminders), increasing parental medication knowledge, and behavioral skill building (problem solving, goal setting).[29–32] A recent trial in pediatric ALL used daily text message reminders and direct supervision to improve oral

medication adherence, and found that for children 12 years old and younger the daily text message intervention did not result in a significant increase in adherence.[33] These previous findings suggest that forgetfulness may not be the optimal target for adherence promoting interventions for young children. Building upon research that documents that medication refusal and avoidance is a common barrier among young children we developed the *CareMeds* intervention which is a caregiver skills training intervention. The *CareMeds* sessions include behavioral practice and rehearsal, goal setting, action planning, and instructions on how to perform behaviors to reduce child medication refusal and avoidance. The goal of this study was to assess the preliminary acceptability and feasibility of the *CareMeds* intervention.

Our hypotheses related to feasibility and acceptability were supported. We met our a priori benchmark of ≥75% enrollment, and met the study retention benchmark of >80% with 100% completing all study procedures. Similarly we met the acceptability benchmark of >8 with mean ratings from 8.75 to 9.75 for all acceptability items, and the reports of caregiver use of behavioral parenting skills met the benchmark of >3.5 with means ranging from 3.89 to 4.22. Notably we implemented this pilot intervention in spring through summer of 2020, when COVID-19 mitigation strategies including school, workplace, and business closures were in effect in New York State where data were collected. Despite these potential barriers, we were able to recruit 75% of potential participants approached and study retention was 100%.

Participants found the intervention to be acceptable and perceived the parenting skills to be helpful in improving medication administration experiences throughout the intervention period. Participants also reflected that they used skills taught in the *CareMeds* intervention in other aspects of their cancer caregiving, including wound care and treatment procedures. These skills may be generalizable across a variety of aspects of pediatric cancer caregiving and provide an important area for future research.

As this was a single-clinic pilot study there was a small pool of families of children in the study age range. Due to this, we included caregivers of children with multiple cancer types, varying times since diagnosis, who were on a variety of daily oral medications. This heterogeneity is a limitation of the study and precludes examination of improvements in medication adherence for this pilot study. An important next step is to examine efficacy of the intervention on medication adherence with a larger sample that is more homogeneous in terms of child's cancer diagnosis, time since diagnosis, and prescribed medication to permit examination of changes in medication adherence.

Overall, our findings show that the *CareMeds* intervention is an acceptable and feasible strategy for caregivers of pediatric cancer patients and warrants future research to examine the efficacy of behavioral parenting skills interventions in improving medication adherence in young children. Similarly, future research is warranted to examine behavioral parenting skills as a target for interventions to support caregivers in other health-related contexts.

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**Table 1.**

Overview of the *CareMeds* Intervention

| Session | Skills Training Covered Session | Model Construct Addressed |
|---|---|---|
| 1 | Understanding the Role of Parents in Successful Medication Administration and Empowering Parents for Success<br>1. Guided evaluation of current routines and barriers<br>2. Setting realistic expectations<br>3. Organizational plans and charts<br>4. Introduction to behavioral reward systems | Forgetting; Logistical Barriers; Inadequate Planning |
| 2 | Communication with Children<br>1. Planning for success<br>2. Communicating with your child<br>3. Positive attention, specific praise<br>4. Behaviors to avoid (e.g., negative talk, yelling) | Support; Psychological Control; Reducing Negative Behavioral Control; Parent-Child Conflict |
| 3 | Empowering and Encouraging Children<br>1. Effective directions<br>2. Active parental involvement, empowering children<br>3. Acknowledging Emotions<br>4. Sharing Duties with your child | Support; Psychological Control; Reducing Negative Behavioral Control; Parent-Child Conflict |
| 4 | 1. Review of positive parenting strategies<br>2. Tips and Tricks for oral medication administration (pill swallowing, direct modeling)<br>3. Planning for the future | Support; Psychological Control; Reducing Negative Behavioral Control; Parent-Child Conflict; Inadequate Planning |

**Table 2.**

Caregiver Reports of Medication-Taking Barriers at Baseline

| Medication-Taking Barriers | R1 | R2 | R3 | R4 | R5 | R6 | R7 | R8 | R9 |
|---|---|---|---|---|---|---|---|---|---|
| Child medication refusal or avoidance | Ignores parental instructions | Barrier not reported | Tantrums; Spits out medicine | Tantrums; Spits out medicine; Will not open mouth for medicine | Barrier not reported | Tantrums; Runs away from parent; Spits out medicine; Will not open mouth for medicine | Tantrums; Hides; Runs away from parent; Spits out medicine; Will not open mouth for medicine | Tantrums; Tries to delay | Runs away from parent; Will not open mouth for medicine |
| Medication Schedule/ Forgetting | Difficulties coordinating across multiple caregivers | Barrier not reported | Barrier not reported | Difficulties managing consistent medication timing; Difficulties managing medication schedule and schedules/needs of other children. | Barrier not reported | Barrier not reported | Barrier not reported | Uses phone timer, sometimes forgets | Barrier not reported |
| Unclear Medication Instructions | Barrier not reported | Refers to other cancer parents and asked questions to providers | Questions about dosing, asked nurses | Unclear when to use some medications as preventative versus symptom management | Unclear how to deal with medication side effects | Barrier not reported | Unclear if certain medications can be given together | Barrier not reported | As needed with pain medications has been confusing to navigate |
| Ensuring Medication Supply/Refills | Barrier not reported | Difficulties coordinating across multiple caregivers | Barrier not reported | Barrier not reported | Barrier not reported | Barrier not reported | Barrier not reported | Barrier not reported | Barrier not reported |

**Table 3.**

Participant-reported Use of Behavioral Parenting Skills After Intervention

| Behavioral parenting skill | Mean | SD | Range |
|---|---|---|---|
| Positive attention | 4.22 | .44 | 4–5 |
| Specific praise | 3.89 | .78 | 3–5 |
| Avoiding negative talk | 4.11 | .60 | 3–5 |
| Effective instruction | 4.00 | .87 | 2–5 |
| Active involvement | 4.11 | .93 | 3–5 |
| Acknowledging emotions | 4.22 | .83 | 3–5 |
| Sharing duties | 4.11 | .78 | 3–5 |

Note. All ratings were on a scale of 1 (Never) to 5 (Always). $N = 9$.