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Enhancing caregivers self-management for their children who require medical technology: A feasibility study for the COPE-STAR intervention

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ABSTRACT

Purpose: To test feasibility of the Creating Opportunities for Personal Empowerment: Symptom and Technology Management Resources intervention for caregivers of children who require medical technologies of tracheostomies and feeding tubes.

Design and methods: Quasi-experimental one group design with measures at baseline and at 4 weeks. Intervention feasibility was tested from August 2019–June 2021, including recruitment, retention, and adherence, and caregiver satisfaction. Caregiver and child characteristics and outcomes were assessed.

Results: Caregivers were enrolled ($n = 22$) and completed ($n = 16$) the study. Caregivers were primarily female ($n = 21$), were predominately Caucasian ($n = 14$, 64%) followed by African-American ($n = 8$, 36%), and Non-Hispanic/Latino ($n = 18$, 82%). Feasibility indicators of recruitment (92%), retention (73%), and adherence (100%) were satisfactory. Outcome measures of management of child's chronic condition, caregiver beliefs about managing their child's symptoms and medical technology, anxiety, and depressive symptoms remained stable. Caregivers agreed that the intervention was useful, easy to use, and acceptable, and had positive feedback.

Conclusions: This is a feasible and acceptable intervention. With further development and efficacy testing, the intervention has potential for use and expansion to a larger population of caregivers of children who require medical technology.

Practice implications: Children who require medical technology have multiple complex chronic conditions and complex care needs at home. This intensive and focused care is provided by informal caregivers who need education and resources for their child's care. This intervention addressed caregiver management of common symptoms and medical technologies of children in the home setting.

Introduction

Children who require medical technology have complex care and technology needs at home for their multiple chronic conditions (Spratling, 2015). The care of the children necessitates intensive and specialized care at home by caregivers (e.g., parents, foster and adoptive parents, grandparents), in addition to primary and specialty clinic visits for their chronic conditions, emergency department (ED) visits and hospitalizations for acute exacerbations. These children are often geographically distant from health care specialists that can best manage health problems (Spratling, 2017) and have high caregiving, health care, and resource needs (Cohen et al., 2011). When at home, caregivers need to be able to manage the symptoms experienced and the technology required by the child. They are a small, but critical part of the population of children with special health care needs in the United States (U.S.), which is currently 19.4% (14.1 million) of children from birth to 17 years of age (2019–2020 National Survey of Children's Health, 2022). When at home, caregivers need to be able to manage the symptoms experienced and the technology required by the child. In addition, caregivers of children with complex care and technology needs commonly experience anxiety and depressive symptoms, and have doubts in their beliefs about managing their child's care (Musil et al., 2015;

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Toly & Musil, 2015). Thus, it is important to develop interventions to enhance caregivers' management of the care of their children who require medical technology at home.

Background

The Creating Opportunities for Personal Empowerment: Symptom and Technology Management Resources (COPE-STAR) intervention consists of six web-based modules on the management of common symptoms (fever, increased respiratory symptoms) and technologies (tracheostomy tubes, respiratory equipment, feeding tubes) and a module for community resources to aid caregivers in finding programs and services available to them in the community (Spratling, Faulkner, Chambers, et al., 2020; Spratling, Faulkner, Feinberg, & Hayat, 2020). The symptoms and technologies were the most commonly found concerns in our review of ED visits and hospitalizations (Spratling, 2017), and commonly described by the caregivers' themselves (Spratling & Lee, 2020). The focus and key content of the modules are summarized in a previously published study protocol by Spratling, Faulkner, Feinberg, and Hayat (2020). COPE-STAR includes evidence-based, theory-based content delivered via a web-based platform. The content is also health-literate, having been developed with a health literacy expert who reviewed the module content and guided revision of modules to ensure that health content was at a low health literacy level. Each COPE-STAR module includes short evidence-based videos with expert explanations and demonstrations of care. These videos also included the child's most common emotions and behavioral responses with the management of their symptoms and technologies, and suggestions for caregivers on how they can best help their child with management of care at home. For example, the tracheostomy tube care module included information on responses of the child as well as the steps of the tracheostomy stoma care.

COPE-STAR was based on the Creating Opportunities for Personal Empowerment (COPE) intervention which is an established, theory-based intervention program (Melnyk et al., 1997; Melnyk et al., 2006). COPE combines aspects from Self-Regulation Theory (Johnson, 1999), control theory (Carver & Scheier, 1982), and the emotional contagion hypotheses (Jimerson, 1987). The COPE intervention combines education and skills about the child's health problems, knowledge of parental role in the child's illness, and addresses the child's most common emotions and behavioral responses with illness and hospitalization. The COPE intervention has also been effective in increasing beliefs about managing their child's care, and decreasing anxiety and depression in studies of parents of hospitalized and critically ill children (Melnyk et al., 1997; Melnyk et al., 2006), premature infants (Oswalt et al., 2013), and children with chronic and terminal conditions (Melnyk et al., 2015; Militello et al., 2016). COPE provides caregivers with objective information about their child's care, while also focusing on enhancing behaviors of the caregiver while they interact with the child during caregiving activities. Caregivers gain practical knowledge to understand their child's care and are simultaneously empowered to manage their child's care. With a better understanding of how to manage their child's care, caregivers may experience better psychosocial outcomes, including less anxiety and depression. Thus, COPE-STAR addresses caregivers' management of their child's symptoms and technology at home, and also their beliefs and ability to manage care for their child, and their anxiety and depression.

After intervention fidelity was established using expert and caregiver review (Spratling, Faulkner, Chambers, et al., 2020), COPE-STAR intervention feasibility was assessed with caregivers. Intervention recruitment, retention, and adherence rates were also measured, and caregiver satisfaction was assessed using an investigator-developed COPE-STAR satisfaction questionnaire and exit interview. Caregiver and child characteristics were assessed, and health literacy was measured at baseline. In addition, the measures of management of child's chronic condition, caregiver beliefs about managing the child's symptoms and medical technology, anxiety and depressive symptoms were evaluated as outcomes of the intervention.

Study methods

Design

The purpose of the study was to test feasibility of the COPE-STAR intervention using a quasi-experimental one group design with measurements at baseline and at 4 weeks post-intervention. COPE-STAR was tested in a sample of caregivers of children aged between 1 and 5 years who required medical technology of tracheostomies and feeding tubes. Caregiver acceptance and caregiver outcomes of management of child's chronic condition, caregiver beliefs about managing their child's symptoms and medical technology, anxiety, and depressive symptoms were also examined for the intervention. Hypothesis testing and power analysis were not conducted for this feasibility study. However, the goal was a convenience sample of 30 caregivers to assess the feasibility of COPE-STAR based on prior recruitment by the principal investigator (PI) and co-investigators, one of whom was a biostatistician.

Setting

Caregiver participants were initially recruited from a clinic that serves children who require a tracheostomy at a large pediatric health care system in the Southeastern U.S. Recruitment was expanded to other clinics within the health care system that serve children who had complex chronic conditions and also required medical technology of tracheostomies and feeding tubes. With the onset of the COVID-19 pandemic, recruitment was limited at these clinics. Thus, final recruitment included social media posts (Facebook®, Instagram®, LinkedIn®, and Twitter®) with a non-profit organization that served children who require a tracheostomy and their caregivers, and with the principal investigator's (PI) university. These posts included a visually appealing image with request for participation, brief inclusion criteria, and contact information for the study along with a simple narrative about the study. The posts were tailored to social media constraints and audiences (e.g., character limit with Twitter®, professional audience on LinkedIn®). Both the organization and university were located in the Southeastern U.S., but had a national presence on social media. Recruitment and enrollment began in August 2019 and the study was completed in June 2021.

Sample

Participants were the self-identified primary caregivers of children aged between 1 and 5 years requiring both a tracheostomy and feeding tube. Inclusion criteria were caregivers who were: 1) parents, foster or adoptive parents, grandparents, or any other non-compensated adult providing care to these children in the home setting, 2) age 18 or older, 3) able to read, write, speak, and understand English, and 4) able to access a computer, tablet or handheld device, or smart phone. Exclusion criteria were those who were employed as paid caregivers (e.g., home nurses, home health aides) and those who were providing care less than one year. The rationale for excluding caregivers with less than one year of experience was to capture caregivers with more extensive caregiving experience at home in order to provide feedback on feasibility of the intervention. Institutional Review Board (IRB) approvals were obtained from the health care system and the university.

COPE-STAR intervention

The intervention module content began with an evidence-based review of current research and practice guidelines. Then, the content was reviewed by experts, including a health literacy expert, to ensure that the content was accurate, current, evidence-based, and at appropriate health literacy levels. Next, the content was transformed into scripts for each module. Lastly, the PI worked with instructional designers and videographers to develop the video modules and post on a password-protected website, focusing on logical organization of content, ease of use, and clarity of modules for caregivers.

The six modules (fever, increased respiratory symptoms, tracheostomy tubes, respiratory equipment, feeding tubes, and community resource) were each five to seven minutes in length. This time length was considered acceptable for presentation of content and review by caregivers. The modules began with a title slide (PowerPoint©), followed by a standard statement in a slide that these modules were not to be used in the event of an emergency, directing the caregiver to call emergency services or seek emergent care if needed. The module proceeded with video demonstrations of care, photos of care demonstrations and equipment, and slides with bulleted information. All of which were narrated by a professional voice actor using the scripts described above.

Intervention fidelity and usability were established through review by experts and caregivers using a systematic, structured process and form (Spratling, Faulkner, Chambers, et al., 2020). Once the web-based modules and website were completed, they were then reviewed by the health literacy expert, intervention researchers, and clinical experts ($n = 8$), and caregiver reviewers ($n = 5$) (Spratling, Faulkner, Chambers, et al., 2020). The reviewers systematically reviewed the modules using the COPE-STAR expert review feedback form which focused on module content, clarity, usefulness, ease of use, and acceptability. This form was adapted from an existing investigator-developed intervention rating previously used in intervention studies for caregivers of stroke survivors (Bakas et al., 2009; Blanton et al., 2019). The feedback from expert and caregiver reviewers were incorporated into the final modules prior to feasibility testing with caregiver participants in the current study.

Measures

All data collection documents were existing reliable and valid instruments or were designed or adapted by the PI with feedback from the original authors and the research team. Constructs and measures, and their time of evaluation (baseline, 4-weeks post intervention) are presented in Table 1. The recruitment percentage was determined by the number of participants enrolled out of the numbers of potential parents that were approached to participate in the study. The retention percentage was calculated by the number of participants completing the study divided by the total enrolled at baseline. Adherence was determined by the percentage of modules completed by caregivers that were retained throughout the intervention period.

The COPE-STAR satisfaction questionnaire and exit interview

The questionnaire and exit interview for caregivers who completed the study were based on a satisfaction instrument previously used in intervention studies for caregivers (Bakas et al., 2009; Blanton et al., 2019). Both the questionnaire and exit interview assessed the intervention in three areas of usefulness, ease of use, and acceptability, and both were reviewed by authors of existing satisfaction instruments (Bakas et al., 2009; Blanton et al., 2019). The satisfaction questionnaire was completed by participants after reviewing each module via a link on the website associated with each module. The exit interview was completed by the PI who has expertise in qualitative research at the end of the 4-week intervention period. The exit interview included open-ended questions about the COPE-STAR intervention related to usability and satisfaction. Caregiver responses to the exit interview were audiotaped and transcribed verbatim for accuracy.

Management of child's chronic condition

The caregiver's management of a child's chronic condition was measured using the Family Management Measure (FaMM, 2022; Knafl et al.,

Table 1
Constructs and measures.

Constructs	Measures	Number of items and scale range	Time of evaluation
COPE-STAR satisfaction questionnaire	Investigator modified questionnaire	Includes items on usefulness, ease of use, acceptability, clarity	4 weeks
Exit Interview	Investigator modified questions		4 weeks
Recruitment	% of sample compared to desired n of 30		
Retention	% of persons who withdraw from study		
Adherence	Number of modules completed/6 modules		
Management of Child's Chronic Condition	Family Management Measure (FaMM) Six scales: -Child's Daily Life -Condition Management Ability -Condition Management Effort -Family Life Difficulty -View of Condition Impact -Parental Mutuality (partnered parents only)	53 items Total score computed based on each scale	Baseline & 4 weeks
Caregiver Beliefs	Adapted scale and two brief scales for confidence in specifically managing symptoms and technology	18 items Total score range 18 to 90; 4 items confidence in managing child's symptoms scale 4 items confidence in managing child's technology scale Total score range 1–7 for each	Baseline & 4 weeks
Depressive Symptoms	Center for Epidemiological Studies- Depression Scale (CES-D)	20 items Total score range 0–60	Baseline & 4 weeks
Anxiety	State-Trait Anxiety Inventory (STAI)	20 items Total score range 10–40	Baseline & 4 weeks
Caregiver and Child Characteristics	Investigator developed demographic instrument that is self-reported by caregivers	18 items	Baseline
Caregiver Health Literacy	Newest Vital Sign (NVS)	6 items Total score range 0–6	Baseline

2011). The FaMM measures how families manage care for a child with a chronic condition and how they incorporate the child's care management into daily life. The FaMM has 53 items and six scales. There are 45 items on five scales for all parents (Child's Daily Life, Condition Management Ability, Condition Management Effort, Family Life Difficulty, and View of Condition Impact), and eight items on one scale for partnered parents only (Parent Mutuality). Questions include, "Our child takes part in activities he/she wishes to despite the condition" from the Child's Daily Life scale, and "We have some definite ideas about how to help our child live with the condition" from the Condition Management Ability scale. Items are scored 1 to 5 (strongly disagree to strongly agree). Total scores are calculated on each scale separately with higher scores on three of the scales (Child's Daily Life, Condition Management Ability, Parental Mutuality) indicate greater ease in managing child's condition; higher scores on the other three scales (Condition Management Effort, Family Life Difficulty, View of Condition Impact) indicate greater difficulty in managing child's condition. Internal consistency reliability for the scales ranged from 0.72 to 0.90 for mothers and 0.73 to 0.91 for fathers, and test-retest reliability ranged from 0.71 to 0.94 (FAMM, 2022). Construct validity has been supported by significant correlations between each of the scales and related established measures of family functioning, child functional status, and child behavior (Knafl et al., 2011).

Caregiver beliefs

The beliefs about managing the child's symptoms and medical technology were measured using a modification of the Parental Beliefs Scale (Melnyk et al., 2014) for caregivers, titled the Caregiver Beliefs Scale (CBS), and the Perceived Competence Scale (PCS; Williams & Deci, 1996) modified for both managing symptoms and managing technology. The CBS is a measure adapted to assess caregiver beliefs about managing the child's symptoms and medical technology. In addition to the CBS, the PCS is a short 4-item measure adapted to assess caregiver confidence in managing symptoms and a short 4-item measure of caregiver confidence in the managing the medical technology. The PCS assessed symptoms and medical technology separately.

The CBS was modified from the PBS (Melnyk et al., 2014), and was reviewed by Melnyk and co-investigators for the current study. The most recent PBS for NICU parents has 18 items divided into three subscales (Parental Role Confidence, Parent-Baby Interaction, Knowledge of the NICU). Items are scored 1 to 5 (strongly disagree to strongly agree) with total scores ranging from 18 to 90. Higher scores indicate more positive parental beliefs and greater confidence in parental role. Internal consistency reliability for the scales ranged from 0.75 to 0.91 for mothers and 0.78 to 0.90 for fathers, and test-retest reliability ranged from 0.84 to 0.92 (Melnyk et al., 2014). The CBS uses specific language for caregivers of children who require medical technology at home and was revised to measure Parental Role Confidence, Parent-Child Interaction, and Knowledge of Medical Technology at Home. For example, the question, "Feel comfortable caring for my baby in the NICU", was revised to the question, "Feel comfortable caring for my child at home with medical technology".

The PCS is a short 4-item, Likert-type scale, based on a motivation theory, which has been adapted and used to assess the degree which participants feel confident about being able to participate in a health behavior or program, or manage a treatment regimen (Williams & Deci, 1996). For the current study, the measure was adapted with permission to measure caregivers' perceived competence in managing symptoms (4-items) and perceived competence in managing technology (4-items). Items are scored 1 to 7 (not at all true to very true) with total scores as an average of items ranging from 1 to 7. Higher scores indicate greater feelings of competence in performing the activity. Construct validity for the PCS has been demonstrated, and internal consistency reliability for the scales ranged from 0.80 to 0.90 (PCS, 2022; Williams & Deci, 1996).

Anxiety

Caregiver anxiety was measured by the State Anxiety (A-State) scale of the State-Trait Anxiety Inventory (STAI) (Spielberger, 1983). The A-State is a 20-item scale that measures current feelings and intensity of anxiety. Items are scored 1 to 4 (not at all to very much so) for anxiety-present items and reverse scored for anxiety-absent items with a total score ranging from 20 to 80 on the A-State subscale. Higher scores indicate greater levels of anxiety. Scores of 40 or above suggest clinically significant symptoms (Spielberger, 1983). Internal consistency reliability for the STAI has ranged from 0.86 to 0.95, and test-retest reliability ranged from 0.65 to 0.75 (Melnyk et al., 2008; Oswalt et al., 2013; Spielberger, 1983).

Depressive symptoms

Caregiver depressive symptoms were measured with the Center for Epidemiological Studies- Depression scale (CES—D) (Radloff, 1977). The CES-D is a 20-item scale that has been used to measure depression in populations with a variety of chronic conditions and in well individuals, including caregivers (Musil et al., 2015; Radloff, 1977; Toly & Musil, 2015). Items responses are scored 0 to 3 with a total score ranging from 0 to 60. Scores of 16 or over indicate risk for clinical depression. Internal consistency reliability for the CES-D has ranged from 0.78 to 0.89 in caregivers of children who require medical technology (Musil et al., 2015; Toly & Musil, 2015). Concurrent validity has been established by clinician ratings (Radloff, 1977).

Caregiver and child characteristics

The characteristics of the caregiver and child were assessed using caregiver self-report to describe the health care needs of the child, and the demographics of the child and the caregiver. Caregiver characteristics included household income, number of persons living in the home, caregiving duration, and caregiver age, gender, education, race, and ethnicity. Child characteristics included age, gender, race, ethnicity, medical diagnoses, and the medical technologies required by the child and the length of time the child has required these technologies. In addition, the number of trained caregivers, home nursing care hours, and use of rehabilitation therapies (physical therapy, occupational therapy, and speech therapy) were also examined.

Caregiver health literacy

The health literacy of the caregiver was measured with the Newest Vital Sign (NVS) which measures the ability to read, understand, and act upon health information (Weiss et al., 2005). The participant reads an ice cream label and answers 6 questions about the label which were asked by the PI. Adequate health literacy is defined as a score of 4 or greater, and is defined as being able to understand, evaluate, and use written and oral health information. Construct validity has been established with existing health literacy measures, and the internal consistency reliability is 0.76 (Rowlands et al., 2013; Weiss et al., 2005).

Procedures for feasibility study

Once potential participants were identified, participants were contacted for a baseline telephone prescreening to confirm willingness to participate, assess eligibility, and schedule an in-person home visit. The PI or research assistants were also available at routine clinic days to discuss the study and conduct in-person screening with potential participants. The first home visit included overview of the study, confirming eligibility, obtaining written informed consent, and baseline measures administered by the PI. After onset of the pandemic, the first home visit was changed to a virtual visit using a secure web-based meeting platform with a verbal consent. Once baseline measures were obtained, the caregivers received instructions and a demonstration of how to reach the web-based modules and a password to access the modules. The instructions included contact information if there were any issues in accessing the site or the modules.

During the 4-week intervention period, caregivers accessed and reviewed the modules. The modules were accessed online via a website by participants to review modules and complete a survey upon completion of each module. The participants received a weekly telephone call reminder to view modules from the PI or research assistants and answer any questions that the participants had about the intervention. The phone calls did not include any additional content or substantive information beyond a reminder and answering basic questions about the study (e.g., module access). The PI was available by phone throughout the intervention period for all participants to answer questions and address any issues.

After the 4-week intervention period, a second home visit or phone call was scheduled and participants completed post-tests and the exit interview which was audio-recorded. If unable to meet in the home and upon onset of the pandemic concluding in-person home visits, follow up was done via telephone to reduce missing data. The COPE-STAR intervention required less than 60 min to review and complete module questionnaires and could be completed anytime over the 4-week intervention period. Pre-tests and post-tests required less than 60 min each to complete. Upon completion of the intervention, caregivers received participant remuneration ($75) for their time in the study. The PI adhered to participant remuneration procedures for the health care system and the university.

Data analysis

Standard data cleaning, identification of missing data, and identification of outliers were completed. Data were analyzed using SPSS Version 28.0 (IBM SPSS Inc, 2021). Descriptive statistics were used to summarize sample characteristics and responses to standard questionnaires. Descriptive analyses and visual data displays were used to assess any observed changes in management of the child's chronic condition, as well as caregivers' beliefs in managing their child's symptoms and technology, anxiety, and depressive symptoms. These were assessed as both process variables and as evaluation of intervention. Since this was a feasibility study, formal hypothesis testing and statistical tests were not conducted (Kraemer et al., 2006; National Center for Complementary and Integrative Health, 2023). The COPE-STAR satisfaction questionnaire was also analyzed using descriptive statistics. Qualitative data from the exit interview were content coded using a descriptive qualitative approach (Sandelowski, 2000; Sandelowski, 2010).

Ethical considerations

Approvals were obtained from the IRB of the health care system and the university (Children's Healthcare of Atlanta IRB# 18–010; approved March 22, 2018). This study was considered minimal risk. All participants met inclusion criteria and completed informed consent. All data were coded with study participant identification numbers and managed in REDCap (Research Electronic Data Capture) at the PI's university (Harris et al., 2009). Database access was limited to key personnel involved in the study. A data safety and monitoring plan was in place; however, no adverse events occurred in the study. All of the study modules directed the participants to seek emergent care in the event of an emergency or life-threatening event as these modules were not intended for use in emergent situations.

Rigor

COPE-STAR is a theory-based, evidence-based, web-based intervention in which intervention fidelity was established using expert and caregiver review prior to feasibility testing. COPE-STAR modules were in a standardized format that could be accessed and viewed on multiple devices (computer, tablet, smart phone). A detailed study manual was developed and used throughout the study to maintain consistent procedures in data collection and participant interactions. Valid and reliable measures were used to collect data by the PI and the PI checked all data after entry into REDCap by trained graduate research assistants.

Results

Feasibility of COPE-STAR

For this feasibility study, 22 caregivers were recruited and enrolled in the study. The recruitment goal of 30 caregivers was not met, despite expansion to other clinic sites and modifications to fully virtual due to COVID-19 pandemic. Of the 49 caregivers who were approached to participate in the study, 25 caregivers did not meet inclusion criteria. Of the 24 eligible caregivers, 2 caregivers declined to participate, resulting in a 92% recruitment rate. Of those 22 participants, 16 caregivers completed the study (baseline and 4 weeks), and six participants were withdrawn due to non-completion of study (baseline only), reflecting a 73% retention rate. Of those 16 caregivers who completed the study, all 16 participants completed all modules which was a 100% adherence rate.

Characteristics of the sample

Caregivers were primarily female ($n = 21$), were predominately Caucasian ($n = 14$, 64%) followed by African-American ($n = 8$, 36%), and Non-Hispanic/Latino ($n = 18$, 82%; Table 2). The caregivers had some college ($n = 7$, 32%) or college graduate ($n = 8$, 36%) and an annual family income of $50,000 or less ($n = 14$, 64%). Caregivers typically cared for two children in the home ($n = 10$, 46%) which included the child who required medical technology. Health literacy was examined at baseline for all caregivers with 86% ($n = 19$) demonstrating adequate health literacy. Child characteristics are also presented in Table 2. Children's medical diagnoses were self-reported by all caregivers enrolled in the study with a wide variety of diagnoses that encompassed common categories of chromosomal and/or genetic conditions ($n = 9$, 41%) and chronic lung disease associated with prematurity ($n = 7$, 32%) with lesser reported categories of conditions as the result of injury, developmental delays and cerebral palsy, cancer, and birth defects ($n = 6$, 27%).

Caregiver outcomes of COPE-STAR

The caregiver outcomes of management of child's chronic condition, caregiver beliefs about managing for their child's symptoms and medical technology, anxiety, and depressive symptoms were examined for COPE-STAR. At baseline, family management and caregiver beliefs were high (FaMM, $M = 170.2$, SD 18.0; CBS + PCS, $M = 84.3$, SD 5.3), and anxiety and depressive symptoms were low (STAI, $M = 35.1$, SD 12.5; CES—D, $M = 10.6$, SD 9.1). The mean of total scores and change scores from these outcomes remained essentially unchanged from baseline to 4-week post intervention measurements (Table 3). Family management was unchanged ($M = 0$, $SD = 170.2$) while caregiver beliefs ($M = -2.1$, $SD = 83.5$) and anxiety ($M = -0.5$, $SD = 34.9$) demonstrated a slight decline. Depressive symptoms ($M = 0.5$, $SD = 10.8$) demonstrated a slight increase.

Satisfaction with COPE-STAR

All caregivers who completed the study ($n = 16$) with 4-week measures agreed or strongly agreed that the intervention was useful, easy to use, and acceptable. Open-ended feedback from the end of module surveys from the caregivers and the exit interview confirmed the usefulness, ease of use, and acceptability of COPE-STAR. Participants described the intervention as well-organized, easy to use, easy to listen and view from various devices, and covered all the basics of care for their child well. The time length and content of the modules were felt to be appropriate for caregivers new to

Table 2
Baseline characteristics of the caregivers (n = 22) and children (n = 22).

Characteristic	Count (Percent)
Child Age	
2	6 (27.3)
3	6 (27.3)
4	5 (22.7)
5	5 (22.7)
Child Ethnicity	
Hispanic or Latino	8 (36.4)
Not Hispanic or Latino	14 (63.6)
Child Sex	
Male	10 (45.5)
Female	12 (54.6)
Child Race	
Caucasian	12 (54.6)
Black or African American	7 (31.8)
Two or more races	3 (13.6)
Caregiver Age	
21–30	9 (40.9)
31–40	11 (50.0)
41–50	0 (0.0)
51–60	1 (4.6)
61–70	1 (4.6)
Caregiver Ethnicity	
Hispanic or Latino	4 (18.2)
Not Hispanic or Latino	18 (81.8)
Caregiver Sex	
Male	1 (4.6)
Female	21 (95.5)
Caregiver Race	
Caucasian	14 (63.6)
Black or African American	8 (36.4)
Caregiver Number of Children at Home	
1	5 (22.7)
2	10 (45.5)
3	4 (18.2)
4	3 (13.6)
Caregiver Education	
Some High School	0 (0.0)
High School Graduate	6 (27.3)
Some College	7 (31.8)
College Graduate	8 (36.4)
Post Graduate Study	1 (4.6)
Caregiver Income	
Less than 10 K	2 (9.1)
10.1-20 K	2 (9.1)
20.1-30 K	4 (18.2)
30.1-40 K	2 (9.1)
40.1-50 K	4 (18.2)
Greater than 50 K	8 (36.4)
Caregiver Years	
1	1 (4.6)
1.5	2 (9.1)
2	6 (27.3)
3	6 (27.3)
4	3 (13.6)
4.5	1 (4.6)
5	3 (13.6)
NVS Correct	
0	0 (0.0)
1	0 (0.0)
2	1 (4.6)
3	2 (9.1)
4	19 (86.4)

tracheostomy and feeding tube care as the more experienced caregivers stated that they wished that they had this resource in the hospital prior to discharge and/or immediately after discharge. Caregivers also described the modules as a 'refresher' for those who have been caring for these technologies for a long time. Lastly, caregivers expressed that they learned new information while being reminded of important care details that they had forgotten or overlooked. The emotional and behavioral support embedded in COPE-STAR were also well-received by participants.

Table 3
Outcome measures of COPE-STAR.

	Baseline			4-Week			Change Scores (Post - Pre)		
Outcome	n	Mean	SD*	n	Mean	SD*	n	Mean	SD*
Family management	21	170.2	18.0	16	170.3	12.5	16	0.0	170.2
Caregiver Beliefs	22	84.3	5.3	16	82.3	6.2	16	−2.1	83.5
Anxiety	22	35.1	12.5	16	34.6	12.1	16	−0.5	34.9
Depressive symptoms	22	10.6	9.1	16	11.1	9.0	16	0.5	10.8

* Standard deviation.

Discussion

In this feasibility study, we were successfully able to recruit and retain caregivers of children who require medical technology for a much-needed intervention study that focused on caregiver management of their child's symptom and technology at home. Based on our findings, COPE-STAR was feasible, and also useful, easy to use, and acceptable for caregivers. Despite the favorable response from participants with the intervention, measures of family management, caregiver beliefs on managing their child's symptom and technology, anxiety, and depressive symptoms remain relatively unchanged. In a cursory review of intervention feasibility studies, the finding of no change pre and post intervention in change scores concurrently with participant acceptability was not unusual in studies of children with autism (Henry et al., 2023) and mothers of infants (Mitchell et al., 2018). Although there was minimal change noted in outcome variables pre and post intervention, the caregivers were managing their child's care well and had positive beliefs about managing their child's care. The caregivers also had low anxiety and depressive symptoms.

Additionally, caregiver health literacy was examined at baseline for all participants and we found that the majority of participants had adequate health literacy. This finding of adequate health literacy in parents or caregivers of children with chronic or complex illness is not new. In a systematic review of studies of health literacy in childhood cancer, the majority of participants from the five studies had adequate health literacy (Lynn et al., 2020). In a study of parental health literacy and outcomes of childhood nephrotic syndrome, 80% (n = 152) of parent participants had adequate health literacy (Borges et al., 2017). The sample in this study also had high educational attainment, and associations between adequate health literacy and higher educational levels have been noted in caregivers of adolescents with sickle cell disease (Yee et al., 2019). Dingemans et al. (2017) examined health literacy in caregivers of children with complex colorectal conditions and found that 70% (n = 98) of caregivers had adequate health literacy at the first clinic visit with scores improving over the next year. This lends to the notion of adequate health literacy in the presence of complex care needs as these were established caregivers of children who required medical technology and had been providing care in the home to their child for at least a year. In retrospect, the exclusion criteria aimed to select a sample of caregivers with sufficient experience in their child's care at home, but excluded those with less care experience at home. The criteria also focused on a specific age group and developmental stages of the children who required medical technology (age 1 to 5 years in the toddler and preschool developmental stages). The reason for this age group and developmental stages of the children were to focus the intervention content, both behaviors of the caregiver with the child and education on care of the child and to capture caregivers of children with similar developmental and care needs. Differences in care needs of children across developmental stages has been found in children with sickle cell disease (Alberts et al., 2021), and in interventions for parents of children with developmental disabilities (Ragni et al., 2022).

Lastly, we found during the recruitment process that many potential participants were paid caregivers and/or had health care backgrounds, such as being nurses, nursing assistants, or home health aides. These potential participants were excluded as we wished to capture caregivers whose knowledge of their child's care was based on typical training provided in the hospital prior to child's discharge with a tracheostomy and feeding tube, and not more formal training given to health care providers. Also, limiting paid caregivers excluded those providers who were in a formal caregiving role. This inability to recruit potential caregiver participants because of their health care experience was unexpected.

Strengths and limitations of the work

While the use of web-based interventions is not new, developing a theory-based intervention targeted specifically for this vulnerable group of caregivers caring for a small, but high healthcare resource utilization population of children who require medical technology is an innovative aspect of this study. The web-based COPE-STAR intervention format that is compatible with mobile devices is accessible for caregivers who are geographically distant from skilled health centers and responsible for their child's medical technology at home. A strength of the study is the use of the theory-based, established COPE intervention as the foundation for the COPE-STAR intervention with a focus on caregivers of children who require medical technology. In spite of the Covid-19 pandemic, the COPE-STAR intervention modules were web-based and easily accessible. The 4-week home visit had a phone visit option, and the in-person baseline visit was easily changed to a virtual visit while maintaining the same procedures. The majority of those caregivers who were recruited and enrolled in the study completed the study without issues in accessing COPE-STAR and had positive feedback about the intervention. Lastly, we also collected data on health literacy to explore potential influence for future studies and use in clinical practice with these caregivers.

Recruitment of these caregivers can be challenging and was heightened with the onset of the pandemic. There was a network of clinics in the healthcare system that provided care to children with medical complexity and we expanded recruitment to these other clinics and subsequently to social media of a non-profit organization and the PI's university. The recruitment using social media in this study demonstrated success in accessing a larger group of caregivers of children who require medical technology, but unfortunately recruitment goals were not met prior to conclusion of the study. In addition, the convenience sample recruited for this study may be subject to selection bias as those with higher education and health literacy may have volunteered for this study more readily than those with lower education and lower health literacy. Lastly, this study may be limited in identifying concerns of parents who have lower literacy with children who have complex care and technology needs, since those with higher literacy and education may have been more willing to participate. Therefore, we were not able to describe results for those with lower literacy.

Implications for practice

Recommendations for further research

Future studies aim to test efficacy and expand inclusion criteria for the intervention to a variety of caregivers by including an expanded group of children in regards to ages and developmental stages, and including children who have been home from hospital less than a year. In addition, anecdotally, several caregivers stated that they wished that they would have had the intervention prior to their child's discharge from the hospital after placement of tracheostomy and feeding tube to use as a resource in preparing to care for their child at home. Lastly, caregiver's health care experience existed a common barrier in recruiting potential participants as exclusion criteria. Some caregivers had such experience prior to caring for their child who required medical technology while others sought formal health care education after experiencing the complex nature of their child's care at home. For future studies, caregiver experience as a health care provider will not be an exclusion criterion, but will be studied to better understand this phenomenon.

Conclusion

Children who require medical technology, specifically tracheostomy and feeding tubes in this intervention feasibility study, enables children to live at home; however, the management of child's care by caregivers at home is intensive and specialized. This study tested feasibility of COPE-STAR with caregivers of children ages 1 to 5 years who required medical technology of tracheostomies and feeding tubes at home. The COPE-STAR intervention focused on how to manage common symptoms and medical technology problems. Caregivers reviewed the intervention for usefulness, ease of use, and acceptability, and completed surveys on management of their child's chronic condition, caregiver beliefs about managing their child's symptoms and medical technology, and anxiety and depressive symptoms. Results suggest that the COPE-STAR intervention was feasible and acceptable for these caregivers, demonstrating satisfactory recruitment, retention, and adherence. COPE-STAR was found to be useful, easy to use, and acceptable to caregivers who participated in the study. With further development, COPE-STAR will be tested for efficacy in a larger study and has potential for expansion to a larger population of caregivers of children who require medical technology. Further, while this study focused on caregivers of children who require medical technology and may not be broadly applicable, the findings support the need for interventions and intervention development for caregivers of children with other chronic conditions, medical complexity, and special health care needs.

Disclosures

The authors declare no conflicts of interest.

CRediT authorship contribution statement

Regena Spratling: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing. **Syeda Zahra Ali:** Formal analysis, Validation, Writing – original draft, Writing – review & editing. **Melissa Spezia Faulkner:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing. **Iris Feinberg:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Matthew J. Hayat:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

None.

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