Resourcefulness Intervention to Promote Self-Management in Parents of Technology-Dependent Children

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The purpose of this randomized controlled trial is to test the effectiveness of a Resourcefulness Training Intervention (RTI©) designed for parent caregivers of technology-dependent children on the parents' (a) psychological and physical outcomes at 6 weeks, 3 months, 6, and 9 months post-intervention; and (b) self-management behaviors (sleep, positive health practices) over 9 months post-intervention. Theoretical underpinnings of the RTI posit that caregivers with greater resourcefulness will experience less stress and are better able to maintain self-management behaviors than caregivers with lower resourcefulness.[28,30] Therefore, RTI© (©1995, Jaclene A. Zauszniewski) is hypothesized to improve a parent's psychological and physical outcomes and self-management behaviors, enhancing his/her ability to deliver care to a technology-dependent child.[15,18,29,47] We plan to measure the effects of RTI on resourcefulness, parent outcomes, and self-management behaviors (sleep, positive health practices).

The specific aims of the study are to: Aim 1: Determine whether the RTI versus Attention Control improves psychological (mental HRQoL, depressive cognitions, depressive symptoms, appraised stress, burden) and physical outcomes (physical HRQoL, chronic stress [hair cortisol]) over 9 months in parents of technology-dependent children, after controlling for covariates (parent race/ethnicity, gender, family income, caregiving duration, and children's functional status, technology type).[32] **Aim 2:** Determine whether changes in psychological and physical outcomes are mediated by changes in parents' levels of resourcefulness based on intervention condition. **Aim 3**: Compare self-management behavior (sleep, positive health practices) over 9 months in parents who received RTI versus Attention Control. **Aim 4**: Explore whether resourcefulness is a mediator between intervention condition and self-management behaviors, controlling for baseline sleep and positive health practices over 9 months. **Aim 5:** Explore the relationship between self-management behavior and parent psychological and physical outcomes based on intervention condition. ***Aim 6*:** Compare target children's healthcare use (ER visits, hospital days) over 9 months based on parent intervention condition.

We hypothesize that: 1) parents receiving the RTI© will have significant improvement in outcomes (psychological and physical health, self-management behaviors) compared with parents in the Attention Control arm, and 2) resourcefulness will mediate the effect of the intervention on all study outcomes.

Parent caregivers of children who require life-saving technology such as mechanical ventilation or feeding tubes must maintain a high level of vigilance 24 hours a day, 7 days a week, due to their child's potential for acute exacerbations and unknown illness trajectory. Their chronic stress related to caregiving while juggling household responsibilities affects their blood pressure, cortisol level,[1-3] sleep patterns,[4-7] and overall physical health,[2,8] compromises self-management behaviors[9] and caregiving capacity,[10-12] and leads to more frequent emergency room (ER) visits and hospitalizations for the technology-dependent child.[13-15] It is not surprising, therefore, that these caregivers report greater levels of stress and poorer psychological and physical health than do caregivers of Alzheimer's patients,[16-18] which dramatically increases their mortality risk.[19,20] Technology-dependent children (approximately 600,000) are among the sickest and most vulnerable subset of children with complex chronic conditions in the United States. They comprise 20% of all children discharged from the hospital to home,[13] yet account for 61% of all healthcare spending for children,[21] up to $110 billion annually.[22] Despite the adverse consequences, only psychoeducational interventions are employed to bolster parents' ability to manage stress and minimize the long-term negative effects on them and their children.

Self-management interventions based on cognitive-behavioral theory significantly decreases appraised stress and improves psychological, physical, and self-management outcomes in many caregiver populations.[23,24 25 26,27] To date, no large scale study has tested such interventions with parents of these children to move the science forward as this study

proposes to do. Resourcefulness Training is a cognitive-behavioral intervention to enhance skill acquisition for stress management that improves psychological and physical outcomes and enhances the care provided to care recipients.[28-30] Our pilot work in mothers of technology-dependent children suggests that this intervention will significantly improve psychological health outcomes and physical health-related quality of life (HRQoL) compared with mothers in a control group.[31] In this 6 week RCT pilot study with 22 mothers of technology-dependent children we explored the feasibility, acceptability, and efficacy of the resourcefulness intervention.[31] **Feasibility:** a majority (95.5%) completed study components (journaling, questionnaires, follow up phone calls). There was minimal subject attrition by two intervention group participants. **Acceptability:** In content analysis of exit interview transcripts mothers in the RT group consistently reported that the intervention helped them to work through challenges in their daily life by raising consciousness regarding strategies to employ and allowed them to reflect on stressful events. "It's a good little card to have because when you go through something stressful, a lot of times you're not thinking like you normally would…the journaling would bring out the reasons that I needed to do the (resourcefulness) things on the card." They also indicated that journaling gave them an outlet to express their thoughts and feelings about the situation and provided stress relief. **Efficacy:** The means and standard deviations for study variables are shown in Table 3. Cohen's d effect sizes for mental health outcome variables between baseline and 6 weeks for the RT intervention group were as follows: Negative Emotion Checklist (d=0.52), Depressive Cognition Scale (d=0.22). This indicates a medium and small effect of the intervention on these mental health outcomes respectively thus a promising result.[31] However, to date, Resourcefulness Training has not been tested in a large sample of parent (mothers and fathers) caregivers or in relation to sleep and positive health practices; we will be the first.

	Inclusion Criteria
1.	Parent primary caregiver (biological, adoptive, or foster mother, father , grandmother or grandfather) for a technology-dependent child based on the Office of Technology Assessment (OTA) classification criteria[32] (Group 1, mechanical ventilators; Group 2, intravenous nutrition/medication; Group 3, respiratory or nutritional support). For children with more than one type of technology, we will follow OTA guidelines for classification.
2.	At least 18 years of age up to 80 years old
3.	Able to speak and understand English
4.	The technology-dependent child must be 17. 4 years or younger and receive care in the home from his/her parent

***For the Intervention Exit Interview- We will include all the above inclusion criteria 1-4 but will add the following:
5. Subjects who were randomly assigned to the Intervention Arm and completed the Resourcefulness Training© session with the interventionist and completed Time 5 data collection.

	Exclusion Criteria
1.	Parents of children with a cancer diagnosis due to the short term use of technology following initial diagnosis and treatment

***For the Intervention Exit Interview- We will include the above exclusion criteria 1 but will add the following:

2. Subjects who were randomly assigned to the Attention Control arm.

We will enroll 100 subjects for this study at UHCMC, 50 subjects from Akron Children's Hospital and 60 subjects from Cleveland Clinic for a total number of 210 subjects.

We will exclude illiterate or non-English speaking individuals due to the amount of reading, writing that must be done as part of the intervention and follow up data collection. Also, our instruments have not been translated into another language.

We will include pregnant women or women who become pregnant while enrolled in the study because many mothers of technology-dependent children are in the child-bearing years. They will be told that they are volunteers and can leave the study at any time.

In addition, we will invite foster parents who (to the best of their knowledge) will be caring for the technology-dependent child long term. This research includes parents of children who are patients in pediatric clinics and hospitals and the majority are not wards of the county/state. Because we will be asking the foster parent questions about the child's type of technological equipment and functional status questions such as their eating and sleeping, a representative of the Department of Children and Family Services (who are the legal guardian of the child) will review and sign a consent form to permit the child's participation (which is limited to information gathering about the child). The PI will explain the study and the foster parent's participation to the representative of DCFS/legal guardian of the child. Once all questions are answered, and providing that the legal guardian agrees to the child's role in the study, he/she will sign the informed consent in the signature block labeled "Legally Authorized Representative" and return it to the PI.

Participant recruitment and enrollment: The RB&C Specialty Clinics (Pulmonary, Gastroenterology, Trach/Vent, Comprehensive Care, Aerodigestive) the RB&C PICU and the Family Learning Center who are associated with this study will distribute the IRB approved study flyer or brochure that contains study staff contact information to potential participants. Potential participants can then call the study staff with questions or to volunteer.

We will also check EMR (All Scripts, Soarian, Whiteboard, Community Record) and do prescreening for potential participants by checking pulmonology and gastroenterology outpatient clinic schedules. We will come to clinic to meet those who meet eligibility to invite them to hear more about the study. If they are interested the study team member will ask about a date/time for appointment. If they are unsure of their schedule we will ask for the best way to contact them to set up appointment at a time/place of their choosing like their home or a library.

Another recruitment strategy will be to post IRB approved study flyers in RB&C/UH Common areas, Family Learning Center and Family Resource Center as well as the RB&C inpatient units such as the PICU that admit technology-dependent children and their corresponding family lounge bulletin boards or posting areas as well as clinic rooms. This will help to gain visibility of our study to enhance recruitment efforts.

We will also distribute our brochures and flyers at family health fairs, specialty organization meetings, support groups, parenting events and gatherings that are frequented by parents of technology-dependent children in Northeast Ohio community to promote awareness of the study by community. In addition, they will be distributed to organizations such as United Cerebral Palsy, Achievement Center of Cleveland, Health Departments that provide services for technology-dependent children and their families. We will also place ads in regional Parenting Magazines and Facebook to help promote recruitment.

We will also use snowball recruitment. While we will not ask participants or potential participants to recruit however some parents may know friends/acquaintances (parents of technology-dependent children) from organizations that they are involved in and ask about letting these friends know about signing up for the study. We would make certain that the participant knows that this is voluntary thus up to them to give our study contact information. If requested, we would give them our study brochure/flyer to pass along to their friend.

The RB&C Specialty Clinics (Pulmonary, Gastroenterology, Trach/Vent, Comprehensive Care, Aerodigestive), the NICU/NICU step down unit on RB&C4 and RB&C 5 and the PICU will identify names and contact information of patients meeting inclusion criteria. A letter describing the study, copy of the consent form and a request for the parent to contact the researcher will be sent by study staff to parents. The letter also informs the parent that study staff will follow-up with him/her by telephone in about 1 week. If the potential participant does not contact the research team in 2 weeks after the letter was mailed, a phone call will be made to invite them to volunteer for the study. This method of recruitment has been successful in the Principal Investigator's previous studies. An information sheet with talking points that is to be discussed with a child over age 7 years will also be included with the letter sent to the mother. Potential participants will be contacted by telephone to assess eligibility and to determine if she is willing to participate in the study. During the telephone pre-screening interview, the nature of the study and the fact that the interview is part of a pre-screening process and does not represent enrollment in the study will be clearly explained to the subject. The questions asked during the interview do not present more than minimal risk or harm to the participants and the interview does not contain any procedures for which written consent is normally required outside of the research context according to 45 CFR 46.117 (c) 2. See attached document for pre-screening question. This question will determine if the child remains dependent on medical technology and thus determines the parent's eligibility for participation in the study. Following this assessment and affirmation of the parent's willingness to participate they will be queried if they received the information sheet with talking points and discussed it with their child. With the above confirmed, the parent will be asked to set up an appointment with the research staff at a mutually convenient time and location.

In addition to the informational letter that will be sent to potential participants identified by study sites, clinic providers will hand out a flyer that gives the study contact information. It will be up to the parent to then contact the study staff to ask questions or to volunteer to participate. The flyer will help to advertise the study.

We will also recruit potential participants using Facebook and Twitter. Both forms of social media will assist in the distribution of the IRB approved study flyer to enhance recruitment efforts. We will include limits of Northeast Ohio since data collection is done face-to-face. This includes development of a Facebook page that includes contact information for study staff and the IRB approved recruitment flyer. "Friend" requests will be made to parent caregiver organizations who have members likely to meet eligibility requirements that includes an introductory letter asking for permission to post the IRB approved study flyer on their Facebook page. The informational letter to be sent with the friend request is attached. We will also recruit using Facebook ads that target users that have connections with technological equipment, technology-dependence and children. Twitter will also be used for recruitment. An image of the IRB approved study flyer will be attached with the tweets. Tweets are limited to 140 characters or less. Tweets will be used and an image of the study flyer will be attached with the tweets. As we find more followers and parent caregiver organizations, we will tag them in our tweets to increase our visibility. "@" will be used to tag or mention an organization and "#" will be used to categorize the tweets. Here are examples of tweets:
@ParentTDkid asks for help with research study to test a way to reduce stress in #parent #caregivers of technology-dependent children in Northeast Ohio.
@ParentTDkid Are you a #parent #caregiver of a child who uses #oxygen #ventilator or #gtube medical technology in Northeast Ohio?
@fpbnursing researching how to reduce stress in #parent #caregivers of children on medical technology in Northeast Ohio. Please contact us to help.

Another recruitment site will be the Cleveland Metropolitan School District. The school nurses who manage the care of children dependent on special technology (medications, tube feedings, treatments) during the school day will send an informational letter regarding this research study and IRB approved study flyer home to the parents/guardians in the child's backpack with their medications, formula for feedings or other supplies. The letter will introduce the study and invite them to call the study office and/or if interested in hearing more about the study they may fill in their name and phone number and mail it to the study office in the self-addressed, stamped envelope provided. The study team would then call the parent (no more than 3 phone attempts) and answer any questions they may have and if they are interested in enrolling in the study invite them to schedule an appointment for informed consent and data collection.

Additionally, Akron Children's Hospital will be a recruitment site. Designated members of Akron Children's Hospital nursing research staff will review and screen specialty clinic appointment lists for parents who meet inclusion criteria. For in-person visits the parent will be approached at the clinic visit and given an IRB approved information sheet specific for Akron Children's Hospital and study handouts such as study flyer, brochure. The information sheet gives a brief description of the study and if the parent is interested in hearing more about the study from the Case Western Reserve University (CWRU) research team they are invited to fill in their name, address, phone number(s) and best times to contact them. For Akron Children's

Hospital telehealth visits a message is sent to the physician through Epic letting them know their patient has been prescreened as a potential candidate for the study. At the conclusion of the visit the physician then asks the parent if they are willing to hear about a research study that is examining ways to decrease stress in parents caring for a child dependent on technology. If they agree the physician will forward the link to the telehealth visit to the Akron nursing research team member after their portion of the visit is finished (link to the visit is sent in a secure chat feature in Epic when it is nurse research team member's turn to talk). The Study Information letter is reviewed with the caregiver and any of their questions are answered. If the caregiver agrees to have information shared with CWRU, the nursing research team member collects their contact information, writes it on the sheet including the team member name and date it was collected and checks the box indicating it was information collected during a telehealth visit. The study coordinator from Akron Children's Hospital (ACH) will send the name, address, phone number, (best time to contact) of potential study participants' who have agreed to be contacted by the CWRU study team for possible study enrollment via secure email to the CWRU Project Manager. The CWRU research team would then phone the potential participant to give more information about the study and answer any questions they may have. If interested in enrolling in the study, the CWRU research team member will schedule an appointment with the potential participant to obtain informed consent, consent to have the technology dependent child's information (i.e., ER visits, hospitalizations during parent's enrollment in the study) released to Dr. Ross and the study team and data collection. CWRU research team will send the parent's completed and signed release of information form to ACH Study Coordinator via secure email. CWRU team will provide set up, training plus meet with the ACH Study Coordinator and recruiting team on recruitment protocols. ACH Study Coordinator will schedule at least monthly teleconference to discuss progress on recruitment goals (approximately 44 potential participants). ACH Study Coordinator to send the CWRU research team the number of ER visits and number and length of hospitalizations for the technology-dependent children of enrolled study participants after a completed, signed release of information form is received.

An appointment will be made to meet with the potential participant at the time and private place of their choosing (that has an area or nook for a private discussion with no outside person within hearing distance of the conversation e.g., their home, public library, their place of employment, child's therapy center such as United Cerebral Palsy Center, Dahm's Clinical Research Unit) to obtain informed consent and collect data. The hair sample will be collected in a private place of the parent's choosing. Study personnel will obtain informed consent and explain to the potential participant that he/she is being asked to provide consent for participation in a research study. It will be explained that participation is totally voluntary and their choice regarding participation will not affect their child's care in any way. Additionally, parents will be given a description of the study, procedures, risks and benefits, confidentiality and voluntary nature of the study including the option to withdraw at any time. Following this discussion, parents will be given the consent form to review. Parents will be given the opportunity to take a few minutes alone to review the written consent form and to make a decision regarding participation. Parents will be assured that none of the data obtained will be communicated to any healthcare personnel at the outpatient clinic or hospital site.

The RB&C Specialty Clinics (Pulmonary, Gastroenterology, Trach/Vent, Comprehensive Care, Aerodigestive) will identify names and contact information of patients meeting inclusion criteria. We will also screen patients being seen in the above clinics using EMR.

There are approximately 180 potential participants at UH and approximately 150 potential participants at Cleveland Clinic who have not been enrolled in one of the investigators previous studies with approximately 15-20 new candidates at each site per year. Akron Children's Hospital has over 250 potential participants and will recruit at least 44 potential participants.

We will conduct the research data collection at a private place of the parent's choosing such as their home, library, place of employment, or restaurant. Our study office is located in the FPB School of Nursing, CWRU.

As described in the above section we will recruit our participants from a number of RB&C Specialty Clinics (Pulmonary, Gastroenterology, Trach/Vent, Comprehensive Care, Aerodigestive). We will also ask the school nurses from the Cleveland Metropolitan School District to send study informational letter and study flyer home to eligible parents. Akron Children's Hospital nursing research staff will also identify and recruit potential participants at their hospital specialty clinics. We will also distribute our brochures and flyers at family health fairs, specialty organization meetings, support groups, parenting events and gatherings that are frequented by parents of technology-dependent children in Northeast Ohio community to promote awareness of the study by community. In addition, they will be distributed to organizations such as United Cerebral Palsy, Achievement Center of Cleveland, Health Departments that provide services for technology-dependent children and their families. We will also use social media such as Facebook and Twitter as well as place Facebook ads to advertise the study. The RB&C specialty clinics will provide lists of eligible participants so that an introductory letter can be sent out to potential participants asking them to contact the study office or in 1 week we will contact them to see if they are interested in participating. We will also be using UH EMR (e.g., Community Record, Sorian) to screen RB&C specialty clinics described above for potential participants and go to the clinic to invite them to hear more about the study. We will also have Cleveland Clinic staff in the above mentioned specialty clinics identifying and inviting parents of their patients to participate in the study.

Consent Process

1. Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe where the consent process will take place:
   Private place of the parent's choosing.

2. The time that will be devoted to the consent discussion:
   Typically, it takes 5-10 minutes depending on how long it takes the participant to read the consent and the number and type of questions.

3. Any waiting period available between informing the prospective subject and obtaining the consent:
   The potential participant will have time between when they schedule the appointment and arriving at the appointment.
4. Steps that will be taken to ensure the research participants' understanding:

To ascertain that potential participants fully understand the study, what is required of them, risks and benefits and their rights as a participant they will be asked to indicate understanding with a "yes" or "no" response. They will also be given an opportunity to ask any questions they have regarding the study.

5. Any process to ensure ongoing consent:
   The participant ensures ongoing consent if they schedule and show up for data collection appointments.

6. The role of the individuals listed in the application as being involved in the consent process:
   All listed on the application as obtaining consent will ask the potential participant if they would prefer to read the consent or to if they'd like the study team member to go through the consent form with the participant. The study team member would then answer any questions they may have about the study.

7. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects:
   No study team member performing consent process will be provider of care for the parent, child. Study team members obtaining consent will be certain to mention that they are volunteers and their care won't be affected in any way by decision to participate or not participate in the study.

1. Give the rationale for the request of a waiver or alteration of the consent process or documentation:
   We need to have a waiver due to prescreening to verify if the individual is eligible for the study.

2. Explain how the research involves no more than minimal risk
   Minimal risk is involved with participation in this study. Physical risks might involve fatigue thus parents will be given a choice to take a break at any point during the interview or intervention session. Writing about the stress of caring for their child in their log (intervention group) might bring out uncomfortable feelings. Parents will be instructed that if they experience distress, they may stop the writing in the online log and contact the research staff. To reduce the risk of a breach in confidentiality we will assign each subject a code number and use that number rather than names to identify parents on all study forms. Identifying data and consent forms will be separated from study data and kept in a separate, locked file cabinet.

3. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants:
   The potential participant retains the right of privacy in that they can refuse to answer the questions about whether their child still requires medical technology such as described in the inclusion criteria, if they care for the child and confirmation of the age of the child.

The prescreening questions do not affect their welfare above that experienced in daily life.

4. Explain why the research could not practicably be carried out without the waiver or alteration of consent.

   Without the waiver to ask the prescreening questions we would not know if they qualify for the study therefore whether we should continue giving a description of the study or setting up an appointment.

5. If you will obtain consent, but not document consent in writing (e.g. over the phone, verbally, electronic survey, etc.), please describe and provide a rationale.

   ☒ N/A

An appointed child advocate will be appointed for a foster child whose foster parent would like to participate in the study. The advocate will act in the best interests of the child. The research is not FDA-regulated. The research is a randomized controlled trial to examine effectiveness of the Resourcefulness Training intervention on the health and wellbeing of parent caregivers. It is hypothesized to be of benefit for the parent caregivers. The research would not be able to be practically carried out to include foster parents in a diverse sample of participants without the waiver of consent because the biological parent does not have custody of the child.

The proposed study is a longitudinal (9-month) RCT in which primary caregiver parents (as defined in inclusion criteria) of technology-dependent children will be randomly assigned to one of two study arms: (1) The **Attention Control arm** will receive weekly phone calls for the first 4 weeks and at 2 and 4 months post-enrollment plus the current standard of care, whereby caregivers phone their healthcare providers when they have questions or concerns; and (2) The **Resourcefulness Training© arm** will receive (a) individually tailored instruction on personal and social resourcefulness skills via the Resourcefulness Video and interventionist, (b) instruction for the online log-writing (via REDCap) so for the parent to describe resourcefulness application, (c) access to the study website with videotape vignettes and Resourcefulness Video, and (d) boosters at 2 and 4 months post-enrollment that will include reinforcement of skills learned and additional online log writing. Measures of parents' outcomes (mental and physical HRQoL, depressive cognitions, depressive symptoms, appraised stress, and burden) and self-management behaviors (appraised/objective sleep, positive health practices) will be obtained at enrollment (T1), then 6 weeks (T2), 3 months (T3), 6 months (T4), and 9 months (T5) post-enrollment to analyze the immediate, extended, and long-term effects of the intervention on parents' outcomes. Chronic stress will be measured by obtaining parents' hair cortisol levels and objective sleep by actigraphy at T1, T3, T4, and T5 to examine changes over time. We will also obtain measures of the mediating (personal and social resourcefulness) variable and covariates (caregiver's race/ethnicity, gender, family income, duration of caregiving, child's functional status, and type of technology).

Research Procedures. The Project Director will notify the data collector of potential participants. He/she will schedule an appointment at a mutually agreed upon time and in a private place of the parent's choosing (e.g., parent's home, library). At that meeting, the data collector will have the parent read the consent form and answer any questions. After written, informed consent is obtained, the data collector will collect baseline (T1) data (questionnaires),

and afterwards collect a hair sample (at the place of the data collection visit) for hair cortisol analysis from the vertex of the parent's head using a standardized protocol.[90] Next, the data collector will instruct the parent regarding the Actiwatch (Philips Respironics, Bend, OR) protocol to measure sleep patterns. This includes application of the Actiwatch on the non-dominant wrist during the enrollment visit with instructions to wear it continuously for 10 days in order to capture baseline sleep patterns. Parents will also receive instructions on a sleep history booklet that will supplement Actiwatch actigraphy data during sleep pattern analysis (e.g., reason for night awakenings). Following data collection, the Project Director will log into a secured database and receive the subject's randomly assigned study arm (Attention Control or Resourcefulness Training). Data collectors will be blinded to all participants' study arm assignment. Randomization will be performed using Minim,[91] a computer minimization stratified randomization program. Minimization helps achieve balance in treatment assignment within strata for targeted covariates.[92] Stratification variables are sex (female, male), race/ethnicity (White non-Hispanic, all others), and OTA[32] group (mechanical ventilator, intravenous nutrition/medication, or respiratory/nutritional support). In keeping with the good clinical practice policy (NOT-OD-16-148), the PI will ensure that all key personnel and staff obtain the Good Clinical Practice Training. The Graduate Student RA will keep a list in our NIH Regulatory Binder.

Attention Control arm. The Attention Control arm will receive study attention via in-person contact at T1, T3-5, weekly phone calls from the Project Director (2-4 minutes) for the first 4 weeks, then phone calls at 2 and 4 months after enrollment to maintain consistency with the intervention arm. The Project Director will ask parents to describe how they/their child are doing. These calls will help to build a relationship with subjects to promote study retention. We recognize that in this group parents may obtain self-initiated caregiving information and support, which will vary among this group. We will use the Information and Support Form to monitor their acquisition of information and support at 6 weeks, 3 months, 6 months, and 9 months post-enrollment. While usual care may vary depending on the healthcare providers seen, all parents assigned to this group can call a physician or nurse to ask specific questions as needed.

Resourcefulness Training Intervention© arm. After we collect T1 data, the interventionist will schedule an appointment to conduct the initial instruction for the RTI© during a session lasting approximately 1 hour either face-to-face in a private place of the parent's choosing or via Zoom using a computer, tablet or smart phone. The interventionist will also conduct all intervention arm follow up. **The intervention includes:** tailored instruction on personal and social resourcefulness skills using the Resourcefulness Video and viewing video vignettes via an iPad, 4 weeks of skills' reinforcement using daily semi-structured online log writing in REDCap, weekly phone calls from the interventionist for 4 weeks after initial face-to-face intervention training, and booster sessions at 2 and 4 months post-intervention (Table 1). Specifically, the interventionist will teach 3 social (help-seeking) and 5 personal (self-help) resourcefulness skills using mnemonic strategies (acronym, practice) to learn them. Subjects will learn to use the acronym to prompt recall of skills. They will be given a wallet-sized, laminated card to keep in their journal and a refrigerator magnet listing these skills as convenient, daily reminders. The interventionist will play the Resourcefulness Video that explains each skill in order, identifying which skills reflect help-seeking, and which reflect self-help. Additional teaching will be individually tailored to each parent's specific situation. The interventionist will ask the parent for examples of how he/she previously has applied each of the skills. If he/she cannot do so, the interventionist will provide examples by asking the parent to describe a recent stressful situation. Together, the parent and the interventionist will develop examples of how each skill can be used for that specific situation. For example, if the parent feels overwhelmed by numerous treatments required by the technology-dependent child and other family tasks, then the interventionist would discuss the use of each skill The

interventionist will also ask the parent to describe other situations where the skills can be applied in the future. Parents will be given the opportunity to ask questions and seek clarification of each skill as needed.

Table 1. Resourcefulness Training Intervention©		
Presentation / content – initial single session with trained interventionist	**Implementation and follow-up – next 28 days**	**Follow up- boosters at 2 and 4 months**
• Show the Resourcefulness Video via iPad or Zoom to teach the 8 RT© skills • Show the video vignettes of parents describing application of resourcefulness skills during caregiving situations via iPad or Zoom • Provide laminated card and refrigerator magnet listing the 8 personal and social resourcefulness skills, using the acronym • Discuss how the RT© skills may be applied/tailored for relevance for caregivers of technology-dependent children • Discuss daily practice of skills/reinforcement by daily writing in a semi-structured log in REDCap accessed via web links sent to participants via email (See Resourcefulness Skills Log Procedure).	• Practice RT© skills daily • Review **RESOURCE** card before completing semi-structured log in REDCap about use of skills during caregiving • Review online content (Video, Vignettes) as desired • Weekly calls to answer questions and remind parents to use the RT© skills and review the RT© card before writing in the semi-structured log. • Text reminders will be sent the morning after any log day is missed and will include the link to the missed day's log OR reminders sent out twice a week noting log days missed (See Resourcefulness Skills Log Instructions).	• Phone call by interventionist to record recall of RT skills, review forgotten skills, ask for examples of skill application since last study contact • Collaboratively plan continued skill application • Begin 1 week of daily writing in a REDCap log with text reminders for any missed days. • Phone call by interventionist one week after booster session

The intervention arm will have access to a website that contains video vignettes demonstrating practical examples of resourcefulness skill application delivered by parents of technology-dependent children who participated in the pilot study. The parents share personal stories of using resourcefulness skills while caring for their technology-dependent children. A total of 15 short (1-3 minute) videotapes are posted on the website, with at least one vignette for each of the 8 resourcefulness skills. We will demonstrate website navigation using an iPad and will give subjects the link and have them access the website during the intervention visit. We will temporarily lend a study iPad with built in Wi-Fi to any intervention participant without internet access through a computer or smartphone during the initial 4-week period and at booster sessions as needed.

The Resourcefulness Video and Video Vignettes will be accessible to intervention arm participants via the secure study website compatible with a household computer or mobile device 24 hours a day, 7 days a week, for the study duration. The videos will be loaded onto Vimeo (approved by UH IRB for IRB# 08-10-30) and embedded in Qualtrics to track user interactions. We will use Qualtrics to enable subjects to access all study components while allowing study staff to track subjects' activities. Qualtrics uses secure, encrypted data collection that restricts access of data to study staff and provides interaction analytics, including frequency of access to the videos.

Practice in conjunction with writing in the REDCap log is another strategy the

intervention arm will use to reinforce and accelerate acquisition of resourcefulness skills and help incorporate them into their daily routine. The interventionist will discuss with the parents the importance of continued daily practice of each of the resourcefulness skills, personalizing the skills by applying them to stressful situations that arise, and if desired, recording their thoughts and feelings related to such events in a journal. More specifically, the parents will be asked to review their acronym reminder card each day. They will check off (yes/no) in their semi-structured REDCap log which resourcefulness skills they used that day and if they found the skill helpful. The log also provides space to express their thoughts and feelings about use of the skills related to caring for their child or daily tasks and any resourcefulness skills they used. They can also write in the log a plan for use of a particular resourcefulness skill. We will ask them to write in their log daily for 4 weeks, at about the same time every day. They will receive up to daily reminders (via text if participant checks box on consent form indicating agreement) based on their rate of completion. The participant preference for timing of reminders (daily or twice weekly) will be asked at first contact with the Interventionist. Their preference will then be noted in the Intervention REDCap Database. To promote adherence, the interventionist will call the parents weekly (5 minutes) for 4 weeks to see if they have questions and remind them about the log. Following instruction regarding the log, subjects will complete a sample entry while the interventionist is present so they have an opportunity for questions. On average, each participant wrote 51.4 specific examples of resourcefulness skill application in her daily life. Prior studies suggest that daily review of the acronym and practice by writing in a log facilitate and reinforce learning of resourcefulness skills and application to stressful events.[93-95] Writing in a log also can significantly improve physical and psychological health[96] and help individuals to process negative emotions and manage stress.[97]

We recognize that, with writing, some will share disconcerting feelings. We have past experience teaching journal writing, analyzing log entries, and reviewing entries for psychological distress. To minimize potential problems, we will review REDCap logs after 1 month. Drs. Musil and Zauszniewski, psychiatric-mental health nurses, will oversee journal analysis for high-risk mental health situations, and follow up as needed. In past experience with journal writing, no psychological distress has occurred. Additionally, we will make weekly follow-up phone calls for the first 4 weeks of the intervention to monitor for signs of psychological distress.

Booster sessions of RTI© will be delivered at 2 and 4 months post-enrollment to refresh the subject's memory of resourcefulness skills and prevent decline in skill usage.[98-100] Booster sessions will be conducted in 10-minute telephone calls. The interventionist will record the parent's recall of skills learned, review skills that have been forgotten, determine whether he/she still has and uses the reminder card and magnet, ask for examples of skill application since the last study contact and which skills were used most often and were the most helpful, and collaboratively plan approaches to promote continued skill application. Parents who are unable to locate the reminder card and/or magnet will be mailed a new one. Because practice is an important component of this intervention, we will ask them to begin 1 week of daily REDCap log as they did for the initial RTI. We will phone them one week after each booster session (2-3 minutes) to inquire about their use of the REDCap log and answer questions about application of resourcefulness skills.

Ensuring Fidelity of the Intervention (Interventionist). Drs. Toly and Zauszniewski will use a systematic procedure to train the interventionist and monitor standardized administration of the RTI©. Examples of each resourcefulness skill and instructions for intervention delivery will be included in the written protocol and given to the interventionist. Before enrollment begins, the interventionist will have two practice sessions with student volunteers, who will present typical problems and questions they may encounter, to assess intervention fidelity. The PI will monitor the first 3 consecutive intervention

sessions. Thereafter, all of the initial intervention sessions will be audio recorded, and the PI and will randomly select 30% of the recordings to monitor for the delivery, receipt, and enactment of the interventions, evaluating them using an intervention fidelity checklist based on the guidelines of Bellg et al.[101] All intervention participants who have audiotaped fidelity checks will be asked to sign a GM-23 consent form prior to any audiotaping.

For participants who receive their intervention session via Zoom will be contacted by the interventionist when scheduled for the intervention appointment that they will need to sign a consent form. If in agreement, emailed a GM-23 consent form via REDCap to be signed prior to the audiotaped intervention session. If any participant refuses to consent it will be noted in the REDCap form. Retraining will occur if 100% accurate delivery of the intervention is not achieved. Once enrollment has begun, the Project Director and Dr. Toly will hold weekly supervision meetings with the interventionist and data collectors to address questions or concerns. Logs will be analyzed for the number of days entries were completed, as well as the number, type, and exemplars of each resourcefulness skill. Dr. Musil, who has used journals and diaries[102,103] in mixed-methods research with grandmother caregivers in addition to our pilot study, will oversee content analysis. Fidelity will also be assessed by noting increasing scores on the Resourcefulness Scale[104] and Resourcefulness Skills Scale[86] over time.

Fidelity of the Intervention (Subject). Fidelity of the intervention (uptake) for each subject (i.e., parent) will be measured 3 ways. First, the 8-item Resourcefulness Skills Scale will determine the frequency of use of resourcefulness skills taught in the intervention.[86] Higher scores indicate greater use. Second, journals for the intervention arm will be analyzed for resourcefulness skills use after the initial 4-week journaling period. In addition, we will analyze journals after each booster session. Finally, the Information and Support Use Form[105] will be used to measure information and support that a parent may have received during the 9-month study period that may affect outcomes for either group.

Intervention Exit Survey. A brief 10-15 minute survey will be administered via REDCap to participants who meet the following eligibility criteria: 1. randomized to the intervention arm; 2. completed the intervention and follow up data collection points; and 3. have not asked to withdraw from the study. This brief survey includes questions about the intervention such as what the easiest/most challenging part was, ways we could make the Resourcefulness Training© better in the future. Eligible participants will be notified (no more than 3 attempts) of the opportunity to complete the Intervention Exit Survey using their preferred mode of contact used in the study and told, that participation is voluntary. If they agree to complete the intervention exit survey, we will inform them of the need to sign a consent form that includes the extra procedure; completion of the intervention exit survey. We will email them the REDCap link for the consent form and once they have signed the consent they will proceed to the intervention exit survey.

Data Collection. The data collectors will collect baseline data (T1) using 12 questionnaires to obtain demographic characteristics of the parent and technology-dependent child and to measure the parental outcomes, self-management behaviors, mediating variables, covariates, and descriptive variables (Table 2). Based on previous experience, this will take about 45 minutes. Following questionnaire completion, a small hair sample from the vertex of the head will be collected, taped, labeled, and placed in foil using a standardized protocol.[90] At the conclusion of the data collection, each subject will be instructed on the use and application of the Actiwatch device for 10 days. Past studies found 9% of nights not scored due to artifact or device not worn.[106] Instructions regarding Actiwatch (and sleep history booklet) return to the study office in the self-addressed, postage paid envelope will be given. Subjects will also be given a sleep history booklet and instructed to record the time they went to bed and woke up, number and reason for night awakenings, and naps. Sleep history booklets have been used in past studies for agreement and interpretation of actigraphy findings; 3-10% were excluded due

to non-compliance.[107] They will be asked to think of a place to keep the sleep history booklet that will serve as a reminder. Participants will be mailed a $5 gift card each time they return the Actiwatch and sleep history booklet to the study office (baseline and 3month, 6 months, 9 months post baseline).

Follow-Up Contacts and Data Collection. Data will be collected for both study arms via mailed questionnaires, emailed link to REDCap surveys (depending on participant preference) at approximately 6 weeks (T2) after the initial delivery of the Resourcefulness Training Intervention or enrollment for the control group. Reminder phone calls will be made by data collectors if questionnaires are not completed within 2 weeks. Data collectors will obtain data about informational, social, caregiving support they may have received related to care of the technology-dependent children at (e.g., phone calls to healthcare providers, amount and type of Internet usage to obtain information, social support or lay caregiving, home nursing) using the Information and Support Form by phone at T2 and in person T3-T5 (3, 6, 9 months post-enrollment). Data collectors will also meet with parents face-to-face at T3-T5 to collect questionnaire data, obtain hair samples, and reapply the Actiwatch and will be blinded to group assignment. Table 2 details timing for all measures. In addition, the interventionist will phone the intervention arm subjects weekly for the first 4 weeks post-enrollment for the initial intervention and at 2 and 4 months post-enrollment for the booster sessions. To maintain consistency of contact with the intervention group, the Attention Control arm will receive weekly phone calls from the Project Director for the first 4 weeks post-enrollment, and then at 2 and 4 months after enrollment. We will also invite eligible intervention arm participants to complete the Intervention Exit Survey (see section Intervention Exit Survey above). If a parent asks a question about the care of their children, they will be referred to their healthcare provider.

Technology-Dependent Child Death. If a technology-dependent child dies during the study period, the Project Manager will send a condolence card to the family and obtain descriptive data about the date and cause of the child's death in the Electronic Medical Record. Data regarding the technology-dependent child's death will not be collected by ACH staff.

Children Who No Longer Require Technology. Parents whose children no longer require medical technology will remain in the study, and their data will be analyzed separately.[41] We will document how soon after study enrollment the technology was discontinued. We expect about 5% will have technology discontinued and thus we will enroll additional participants to compensate for this attrition.

Retention Plans. To maximize retention over the 9 months, we will send birthday cards on the parent's and child's birthdays, as well as bi-monthly postcards with an inspirational message and contact information for the study office. Furthermore, we will recruit data collectors who are experienced and comfortable working with families who have children with special needs.

Controlling diffusion of intervention approaches. In our prior work, we found that few participants knew one another, so we believe the threat of diffusion is low. We recognize the possibility of the Hawthorne effect impacting our data. Therefore, the research team believes that it is vital to reliably track the amount of information and emotional support obtained by parents in all study arms and expect that any Hawthorne effect will be equally distributed because we are collecting the same information for both arms.

Measures. Study measures will be obtained at baseline (study enrollment), 6 weeks, and 3, 6, and 9 months post-enrollment, time frames selected based on prior work with caregivers and RTI© in order to capture variability over time. Table 2 shows study measures and measurement points. We chose measures based on our prior work with caregivers that are psychometrically sound and/or recommended by NIH as common data elements to facilitate cross-study analysis and increase the scientific impact of our study analyses.

Parent Outcome Variables: Parent Mental and Physical HRQoL will be measured by the 10-item Patient-Reported Outcomes Measurement Information System (PROMIS^{R}) Short Form v.

1.2 Global Health Scale.[108,109] The PROMIS^{R} measures have been extensively tested and demonstrate excellent psychometric properties. Depressive cognitions will be measured by the 8-item Depressive Cognitions Scale[110] to assess cognitive symptoms that precede depression;[111] higher scores indicating more depressive cognitions.[110,112] Depressive symptoms will be measured by the 8-item PROMIS^{R} Short Form v 1.0-Depression 8a.[113] A clinically significant *T* score of 60 (raw score ≥22) requires action steps (see Human Subjects).[114] Appraised stress (subjective) will be measured by the 10-item Perceived Stress Scale[115] (NIH Toolkit); higher scores indicate greater stress. The level of chronic stress will be measured by a hair cortisol sample that measures cortisol level over the past 3 months.[68,90,116] Caregiver burden will be measured using the Zarit Burden Interview-12, a 12-item tool assessing caregiver burden, with higher scores indicating higher burden.[117] While originally developed for caregivers of older adults, it has been successfully used with parent caregivers.[118,119]

Self-Management Behaviors: Appraised sleep quality will be measured by the Pittsburgh Sleep Quality Index (PSQI), a 19-item, self-report measure of sleep disturbance in adults[120] It provides a global score that includes 7 subscale scores: sleep quality, sleep duration, sleep latency, sleep disturbance, habitual sleep efficiency, daytime dysfunction, and sleep medications over the past month. A global sum of ≥5 indicates a "poor" sleeper.[120] Objective sleep patterns (total sleep time, wake after sleep onset [WASO], sleep latency [time to fall asleep], sleep efficiency [% of time spent in bed sleeping], longest sleep period, night-to-night instability [mean square successive differences])[4] will be measured using the Actiwatch (Philips Respironics, Bend, OR) for actigraphy. Actigraphy is a valid and reliable measure of sleep that is highly correlated with the clinical gold standard, polysomonography,[121,122] but more practical for caregivers. The Actiwatch contains a calibrated accelerometer that can interface with a

Table 2. Variables and Measures

VARIABLE	MEASURE	TIME OF MEASURE				
Parent Outcomes		**Enroll**	**6 Wk**	**3M**	**6M**	**9M**
Psychological Health						
Mental HRQoL	PROMIS^{R} (SFv1.2- Global Health)	X	X	X	X	X
Depressive Cognitions	Depressive Cognitions Scale	X	X	X	X	X
Depressive Symptoms	PROMIS^{R} (SFv1.0- Depression 8a)	X	X	X	X	X
Appraised Stress	Perceived Stress Scale (NIH Toolkit)	X	X	X	X	X
Burden	Zarit Burden Interview-12	X	X	X	X	X
Physical Health						
Physical HRQoL	PROMIS^{R} (SFv1.2- Global Health)	X	X	X	X	X
Chronic Stress	Cortisol (Hair)- objective	X		X	X	X
Self-Management Behaviors		**Enroll**	**6 Wk**	**3M**	**6M**	**9M**
Appraised Sleep Quality	Pittsburg Sleep Quality Index- subjective	X		X	X	X
Objective Sleep Patterns	Actiwatch Actigraphy	X		X	X	X
Positive Health Practices	Personal Lifestyle Questionnaire	X	X	X	X	X
Mediating Variable		**Enroll**	**6 Wk**	**3M**	**6M**	**9M**
Resourcefulness: Personal	Resourcefulness Scale (Personal Resourcefulness Subscale)	X	X	X	X	X
Resourcefulness: Social	Resourcefulness Scale (Social Resourcefulness Subscale)	X	X	X	X	X
Covariates		**Enroll**	**6 Wk**	**3M**	**6M**	**9M**
Parent: Race/Ethnicity, Gender, Family Income, Duration of Caregiving for Technology-Dependent Child	Enrollment Form	X	X	X	X	X
Technology-Dependent Child:						
Functional Status	Functional Status II-Revised	X	X	X	X	X
Type of Medical Technology	Technology Dependency Questionnaire	X	X	X	X	X
Descriptives		**Enroll**	**6 Wk**	**3M**	**6M**	**9M**
Parent:						
• Age, Marital Status, Education	Enrollment form	X				
• Home Nursing Support Services, Amount of Lay Caregiving Assistance	Information and Support Form	X	X	X	X	X
• Interpersonal Support	Interpersonal Support Evaluation List	X	X	X	X	X
Technology-Dependent Child:						
• Age, Gender, Primary Diagnosis	Enrollment Form	X				

computer. Actigraphic data during 1-minute epochs are then scored as sleep or wake in relation to a defined threshold. Actigraphy data will be reviewed by Co-I J., trained in processing actigraphy data, using the sleep history booklet to assist in identification of bedtime in-bed

periods. Actigraphy will be analyzed using Actiware software (Philips Respironics, Bend, OR) to apply sleep/wake scoring algorithms, and summary reports will be generated to return the objective measures of sleep described above. Positive health practices will be measured using the Personal Lifestyle Questionnaire, a 24-item self-report tool that measures exercise, substance use, nutrition, relaxation, safety, and general health promotion.[123,124] Higher scores indicate more positive health practices.

Mediating Variable. Personal and social resourcefulness will be measured by the 28-item Resourcefulness Scale that measures personal (16 items) and social (12 items) resourcefulness skills.[104] Higher scores indicate greater resourcefulness.

Covariates. Parent covariates (race/ethnicity, gender, family income, duration of caregiver role) will be recorded on the enrollment form. Child covariates. Functional status will be measured using the 14-item Functional Status II-Revised (FS II-R);[125] higher scores indicate higher function. The type of technology used by the child will be recorded on the PI-developed Technology Dependency Questionnaire and analyzed using dummy codes for regression.

Intervention Exit Survey. This survey will be delivered to eligible intervention arm participants to assist with future intervention delivery improvements.

Descriptives. The parent's characteristics (age, marital status, education) will be recorded using the enrollment form. The amount of outside lay caregiving assistance and home nursing will be recorded on the Information and Support Form. Interpersonal support will be measured by the 12-item Interpersonal Support Evaluation List (ISEL).[126,127] Higher scores indicate greater social support. The technology-dependent child sample characteristics (age, gender, primary medical diagnosis) will be recorded on the enrollment form.

Design and methods to achieve robust and unbiased results (Rigor). This carefully powered 9-month RCT is designed to achieve robust results incorporating safeguards to reduce error. First, we have selected psychological measures with excellent psychometric properties. Measures to assess biological processes (sleep, cortisol) were chosen for their ability to directly measure the process or marker being studied—a gap identified in prior research—thus reducing another source of error. Second, we have developed our analytic plan to incorporate relevant covariates and will achieve unbiased results by including an additional statistician to evaluate reproducibility of results via a confirmatory analysis of study findings. By comparing analytic results from two statisticians, we will establish reproducibility of results and ensure the robustness of our findings.

Study results will be generalizable to parent caregivers of technology-dependent children with complex chronic conditions. We have broad inclusion criteria, increasing generalizability of results. All parent caregivers' children will be technology-dependent with a range of complex, chronic conditions. Based on prior work, we expect our sample to range in age from 18-65 years and represent all income levels. Some parent caregivers may be up to 80 years old. We will also have representation of male caregivers, often underrepresented in such research.

Data Management. We will use numbers rather than names to identify parents on all study forms to maintain confidentiality. Identifying data and consent forms will be separated from the study data and kept in a separate, locked file cabinet. Data will be entered into password-secured, encrypted computer files. Each subject will have a separate file stored in a locked cabinet. The data will be stored on a server folder accessible to only the PI, research staff, and Information Technology department staff. A Study Operations Manual will include procedures for subject recruitment, data collection and coding, and data management. The Graduate

Student Research Assistant will be responsible for the day-to-day data management of the study.

Estimated time required (minutes)	Pre-Screening	Time 1	Time 2	Time 3	Time 4	Time 5
	1 minute					
Data Collection	N/A	60	45	45	45	45
Weekly calls x first 4 weeks (control group)		2-4	2-4	2-4	2-4	
Weekly calls x first 4 weeks (intervention group)		5	5	5	5	
RTI session with Interventionist after random assignment		60				
RTI booster sessions at 2 months & 4 months post intervention		10	10			
RTI booster follow up call 1 week after booster session at 2 months & 4 months post intervention		2-3	2-3			

Sample Size and Justification. Using data obtained from the pilot study, parents' outcomes at baseline and 6 weeks in the control and intervention arms (e.g., standard deviation and correlation between outcomes measured at baseline and 6 weeks), a two-stage model for longitudinal data that assumes an exchangeable correlation structure among pairs of outcomes measured at five time points, and a Bonferroni corrected, two-sided significance level of 0.05/2 = 0.025 to account for multiple comparisons between the two arms, the detectable mean differences (*d*) in the monthly rates of change in each outcome between two arms that will be detected with ≥80% power based on a total sample size of 144 (72 subjects per arm) are as follows: parent's depressive cognitions (*d = 0.22*) and parent's HRQoL (*d = .45*). Based on prior longitudinal research with caregivers,[41,85] we expect a 20-30% attrition rate by Month 9. We will enroll a total of 210 parents (105 per arm).

ANALYSIS

We hypothesize that: 1) parents receiving the RTI© will have significant improvement in outcomes (psychological and physical health, self-management behaviors) compared with parents in the Attention Control arm, and 2) resourcefulness will mediate the effect of the intervention on all study outcomes.

Preliminary Analyses. Exploratory data techniques will be *performed by the junior statistician* to examine univariate characteristics (central tendency, dispersion, and distribution) of demographics and covariates measured upon randomization in each arm. These exploratory techniques will be based on proportions (in the case of dichotomous variables) and medians and/or means (in the case of variables measured on an interval scale). Due to randomization, no formal tests of these variables will be performed because any imbalance between arms is known to be due to chance. Profile plots will also be used to describe the participant-specific (parent) and arm-specific trends for each outcome over the five time points. Differentiation in outcomes, due to the sex, will be studied in the preliminary analysis using descriptive statistics and graphs (e.g. box plots). In the regression analyses (presented below) we will control the effects of sex as

a covariate while studying various relationships between outcomes and intervention or mediators.

Primary Analyses.

Aims 1 & 3: Analysis of the monthly rate of change for each parent outcome in each arm will be estimated via linear mixed models and fit using SAS PROC MIXED.[128,129] Each model will include a random intercept and slope (possibly modeled using a polynomial spline) to account for between-subject variance in each outcome over time. Conditional on these random effects, we will explore within-subject variance in each outcome over time using different residual covariance structures and select the most appropriate structure using likelihood-based criteria. Fixed effects will include a continuous variable to represent time since randomization, an indicator variable to represent the intervention, and stratification factors used during randomization (facility, OTA technology group, race/ethnicity). Assuming a linear rate of change over time, the regression coefficient of the terms representing interactions between time and the intervention indicator variable will be used to estimate the difference in the monthly rate of change in each outcome between arms.

Aim 2 & 4: To determine if resourcefulness mediates the effect of the RTI© on parent outcomes (psychological and physical health, self-management behaviors), a theory-based causal mediation model[130,131] will be fit using separate linear mixed models of parent outcomes at 3 months after randomization that adjust for the intervention indicator variable, stratification factors, and the mediator at 6 weeks after randomization. This model will allow us to decompose the total effect of the RTI on parental outcomes at 3 months into direct and indirect (or mediated) effects and estimate the proportion of the total effect that is mediated. Variance estimates and 95% confidence intervals will be estimated using a bootstrapping procedure based on 1000 bootstrap samples. To more fully explore the temporal pattern of mediated effects, we will use similar models to estimate the mediated effect using measurements of the mediator and parental outcome taken at other time points as well (e.g., total effect of RTI© on parent outcomes at 6 months that are mediated by personal and/or social resourcefulness at 3 months).

Aim 5: To assess the relationship between self-management behavior and parent psychological and physical health outcomes, we will use correlational and regression analyses. The effect of RTI© on outcomes will be estimated after controlling for important covariates in the structural equation model (SEM). Also, we will study parental psychological and physical health outcomes and its association with sleep (or positive health practices), using the SEM framework. The SEM is a general, flexible, powerful, and comprehensive methodology for representing, estimating, and testing a network of relationships among variables of interest. By the use of SEM, we will be able to develop a hypothetical model or path diagram that allows for specification of relationships and the directionality of the relationships among the variables of interest. These exploratory models or path diagrams that are derived from this study will be a basis for further study/validation. In the model fitting, we will use the method of maximum likelihood estimation (MLE) for estimating parameters.

To account for any multiple comparisons, a Bonferroni-corrected, two-sided significance level will be applied to all analyses for all aims. Additionally, we expect some level of missing data at each time point. To adjust for the missing data in all mixed-models analyses, we will apply pattern-mixture models to each model to ensure that missing data is adequately accounted for in each analysis. In contrast to a “completers only” approach, pattern-mixture models will provide a consistent and asymptotically efficient estimate of the effect of intervention on the monthly rate of change in parent outcomes when data is missing not at random.

Aim 6: We will analyze the technology-dependent children's ER visits, hospital days over 9 months using a Poisson regression model that adjusts for the intervention indicator variable and important covariates. This model will allow us to compare the relative rate of ER visits, hospital days between the two arms.

Secondary Analyses. To obtain more precise estimates of the intervention effect on the time point interval rate of change in each parent outcome, additional multivariable analyses will characterize and estimate the relationship between potential covariates at baseline and each outcome. For continuous variables lacking a linear relationship with the outcome, appropriate transformations or categorization will be considered. For nominal and ordinal variables, the number and type of categories will be considered to obtain the optimum relationship, if any, with the outcome. Based on a two-sided significance level of 0.15, any baseline covariate found to be associated with the outcome will be included in the model described for the Primary Analyses.

Modification of the intervention effect on the monthly rate of change in each parent health outcome will also be tested in each model by including an interaction between a prespecified effect modifier measured at baseline, the intervention indicator variables, and the variable representing time since randomization. Should an interaction be detected based on a two-sided significance level of 0.05, the monthly rate of change in each outcome will be estimated in each of the arms for each level of a categorical effect modifier or at the 25^{th}, 50^{th}, and 75^{th} percentiles of a modifier that is measured on an interval scale. A similar analysis will be conducted to examine possible effect modification of the intervention effect on positive health practices, by including an interaction between the intervention indicator variables and the prespecified effect modifier.

Sensitivity analyses will also be applied to all mediation models described for the Primary Analysis to evaluate the assumption of sequential ignorability (no unmeasured confounders of the association between the mediator and each parent outcome). As described by Imai et al.,[131] this analysis assesses how large an effect an unobserved confounder must have on both models to cause a nonsignificant mediated effect.

There are few risks to participants. A potential emotional risk during the interview is that recalling information regarding their child's course of illness and home management difficulties may make some parents uncomfortable. The interviewer will be vigilant to assess the parent's discomfort. Parents experiencing considerable discomfort will be asked if they wish to stop the interview and will be given supportive assistance by the interviewer. The parent will then be told to contact their primary care provider and given a resource sheet with the number of United Way First Call (211) to access on-call mental health professional services in their local area or Cuyahoga County 24-Hour Mental Health Crisis Information and Referral Hotline (216-623-6888). If any participant is noted to have a level of depressive symptoms above the recognized clinical *T* score of 55.1 (raw score ≥16- mild depressive symptoms) on the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form v 1.0-Depression 8a measure, he/she will be told of the findings and given instructions to contact his/her primary health care provider and the resource sheet with mental health contact phone numbers as above (See Mental Health Resources Decision Tree). Any parent expressing signs or symptoms of major depression (i. e., hopelessness and/or helplessness) in the enrollment interview, Resourcefulness Training appointment, telephone follow-up, journal writing, data collection appointments, booster sessions, or parents with a PROMIS-Depression 8a score of ≥22 (moderate to severe depressive symptoms) or a Depressive Cognitions Scale score of ≥7, will be assessed for imminent risk of suicide by asking if they have had any thoughts of harming

themselves in any way or perhaps killing themselves. If the answer to any portion of the question is “yes” the participant will be told of a concern for their safety and the necessity for the interviewer to contact the Crisis Team from the Cuyahoga County 24-Hour Mental Health Crisis, Information and Referral Hotline immediately. The consent form will specifically discuss this risk. The research team members will notify the PI of any need to activate the above plans for the Crisis Team or referral to the 24-Hour Mental Health Crisis Information and Referral Hotline. Throughout the study, all research team members in contact with subjects will also assess for other psychiatric symptoms that might require intervention from the Crisis Team or the above 24-Hour Mental Health Hotline. Co-Investigators Musil and Zauszniewski are psychiatric nurses and can provide consultation to the Interventionist and data collectors when needed. Also, physical risks might involve fatigue due to the length of time (about 45 -50 minutes) needed to answer the study questions and about 1 hour for the Resourcefulness Training© intervention and practice journal entry. There is a slight inconvenience for all participants will need to take scheduled phone calls as per protocol, schedule time to meet with data collectors, wear Actiwatch at specified times and mail them back to study office. The intervention group will experience slight inconvenience due to time for intervention session, time to write in semi-structured journal 2-3 minutes daily for 4 weeks and 1 week booster journals (2 months, 4 months post intervention). Finally, there is a minimal risk to loss of confidentiality with collection of data particularly with the collection of Personal Health Information regarding the technology-dependent child. The consent form will specifically discuss these risks.

There is a slight risk of developing skin irritation from the Actiwatch. The participant will be instructed at enrollment that if any redness of the skin develops in the area where the watch is worn they are to remove it and contact the study office. There is also a very rare risk during hair sample collection of a minor scalp laceration (a cut) and infection related to same.

All participants are volunteers and non-participation and withdrawal from the study are alternatives to study participation. Parents will be told that they may withdraw from the study at any time. There are no risks to non-participation or withdrawal from the study. The Project Director (at recruitment) and the data collectors (at enrollment) will explain that participation or non-participation will have no effect on the type, quality, or nature of medical care that the technology-dependent child receives, and that all research data will be obtained by an Interventionist or data collector and will not be communicated to any healthcare personnel at the healthcare facility.

Writing about the stress of caring for their child in their journal might bring out uncomfortable feelings. Parents will be instructed that if they experience distress, they may stop the journaling and contact the research staff. In addition, they will be instructed to tell the research staff about these feelings during the weekly follow-up telephone calls. If needed, we will provide emotional support and refer them to mental health resources such as the 24-Hour Mental Health Crisis, Information and Referral Hotline as detailed in the above description of risks. We have past experience teaching journal writing, analyzing journal entries, and reviewing entries for psychological distress. To minimize potential problems, we will collect journals after 1 month. Drs. Musil and Zauszniewski, psychiatric-mental health nurses, will oversee online log writing analysis for high-risk mental health situations, and follow up as needed. In past experience with journal writing, no psychological distress has occurred. Additionally, we will make weekly follow-up phone calls for the first 4 weeks of the intervention to monitor for signs of psychological distress.

To reduce the risk of a breach in confidentiality we will assign each subject a code number and not include names on any study materials. UH REDCap will be used for any prescreening, data collection and any follow up information. In any sort of report we might publish, we will not include any information that will make it possible to identify subjects. Any hard copy lists will be kept in a locked file and access will be limited to the researchers, the review board responsible for protecting human subjects, regulatory agencies, and sponsors and funding agencies. Voice recorders will be stored in a locked file cabinet following data collection. The list linking the participant name, contact information and study ID will be destroyed 5 years after completion of the study. Participants will also be told that individual responses will not be shared with others. Participant names will not be used in any reports of the study.

All information obtained during data collection will be kept confidential and will be disclosed only with the participant's permission or as required by United States or Ohio law such as abuse of their children. If disclosure is made by the participant regarding harm of themselves or others, the appropriate agencies such as the 24 Hour Mobile Crisis Team or the Ohio Department of Job and Family Services (216-696-KIDS) will be notified as per study adverse event/ serious adverse event, abuse protocol. If a participant discloses domestic abuse/violence to a member of the study team the study adverse event, serious adverse event, abuse protocol will be implemented that includes giving the phone number to the Domestic Violence Hotline: 1-800-799-SAFE.

To maintain participant privacy, all interviews will be conducted in a private area in a place of the mother's/father's choosing such as her/his home, public library, place of employment, private place in a coffee shop or the Dahms Clinical Research Center. Privacy will be maintained as well in the procedures for identifying participants as described above. Participants will be mailed an introductory letter prior to study staff making telephone contact. We will respect their wishes related to the best way to maintain contact with them (phone, text, email).

Facebook and Twitter will be used to post the IRB flyer about the study. A "Friend" request will be sent to parent caregiver organizations who have members likely to meet inclusion criteria along with an introductory letter about our study and the request to post our recruitment flyer. The organization can make a decision to accept or reject the request to post our study flyer. Potential participants reached through either Facebook or Twitter would then self-identify and voluntarily contact us to hear more about the study and decide on participation. When they contact the study staff they will be screened for eligibility including residence within Northeast Ohio for face-to-face data collection.

Participants may receive some benefit from the stress reducing methods used in this study (Resourcefulness Training, writing in log). The potential risk for emotional distress is minimal and reasonable given the potential benefit for reducing stress and improving a parent's psychological and physical health outcomes and self-management behaviors (sleep, positive health practices). This study will benefit other families by aiding in our understanding of what methods help parents reduce stress and promote optimal psychological and physical outcomes and self-management behaviors when they are caring for a technology-dependent child. It is hoped that parents who participate in the

Resourcefulness Training arm of the study will feel more confident as they implement resourcefulness skills over the intervention period and will have a reduction in negative impact of caregiving over time. In addition, it is believed that the Resourcefulness Training intervention will enhance the care delivery by the parents and decrease the number of emergency room visits and hospitalizations.

Possible causes for the participant to be withdrawn from the study include that the child with special medical technology has become too ill or has died. The participant may decide to withdraw from the study due to lack of interest to complete the remaining questionnaires at T2, T3, T4, T5 or that she/he is not interested in continuing to complete the journal writing. If the participant indicates an intent to withdraw from the study, she/he will be invited to share reasons for desire to withdraw from study. Participants will not be followed after they have voluntarily withdrawn from the study unless they indicate that they wish to be contacted in the future for any follow-up studies. If the child has the special medical technology removed during the course of their parent's participation in the study we will continue to conduct data collection but will note removal of technology in analysis.

There is no reimbursement for parking and meals but an incentive will be given to participants for their time and inconvenience. Participants will be given a $25 gift card at each of 5 time points following completion and return of the questionnaires. The total payment will be $125 over the study time if they complete all portions (5 data collection points) of the study. They will also receive a $5 gift card each of the 4 time points they need to return the Actiwatch and sleep history booklet to the study office. The total payment for returning these items each time (4 time points) is $20.

Data and safety monitoring will be conducted to determine if data collection should be altered or stopped. Every 6 months the DSM Committee will assess the risks and benefits of the study by reviewing individual adverse events and unanticipated problems that have occurred during the study. Data monitoring will include a review of the accuracy, validity, reliability and completeness of data collection. Dr. Toly, the principal investigator will make the decision related to altering the study in collaboration with the committee if more than two mothers/fathers experience significant discomfort or distress that required a referral to United Way First Call.

Data and safety monitoring will be conducted to determine if data collection should be altered or stopped. Every 6 months the DSM Committee will assess the risks and benefits of the study by reviewing individual adverse events and unanticipated problems that have occurred during the study. The committee members are not part of the research team. This committee will review data on this study regarding 1) study safety, including auditing selected cases for compliance with IRB requirements, conformance with informed consent requirements, verification of source documents, and investigator compliance; 2) minimizing research-associated risk; and 3) protecting the confidentiality of participant data. In addition, it will review (1) all causes of mortality and (2) issues with participation. The rate of recruitment refusal (percent and reasons) and subject

attrition (percent and reasons) will be tracked and reported at these reviews. Differential attrition from the intervention and control arms also will be monitored. Written reports will be developed and submitted to the committee by the CWRU PI, Dr. Toly, the principal investigator will make the decision related to altering the study in collaboration with the committee if more than two mothers/fathers experience significant discomfort or distress that required a referral to United Way First Call. Dr. Toly will be responsible to submit written reports to any funding agency within 2 weeks of the meeting. If concerns or problems are identified by the SMC, they will be reported to the IRB and funding agency via email by Dr. Toly within 3 business days after they are identified. If there are recommendations made by the SMC, the action plan for response or notice of any actions taken by the IRB regarding the research and any responses to those actions will be provided to Funding Agency Officials within 2 weeks.

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