*[USE THIS BIOMEDICAL PROTOCOL TEMPLATE IF YOUR PROJECT INVOLVES **ANY** PHYSICAL CONTACT OR MEDICAL INTERVENTIONS WITH PARTICIPANTS]*

INSTRUCTIONS:

- *Use this template to prepare a document with the information from the following sections.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research.* ***Do not delete any sections, questions, or help text and mark "N/A" if sections do not apply***
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*

PROTOCOL TITLE:

Intervention Pilot with Parents of Technology-Dependent Children
*(***Modified 6/1/18 and approved by UHCMC IRB)**

PRINCIPAL INVESTIGATOR:

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If the principal investigator's primary role at UH is resident, fellow or student, identify a faculty advisor.

*Name **N/A***
Primary Department
Telephone Number
Email Address

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):

Pulmonology- Dr. Kristie Ross is the UH Sponsor

VERSION NUMBER:

Include the version number of this protocol if assigned by an outside entity.

I am not sure of the version number.

DATE:

Include the date of submission or revision.

It is the current version as of May 21, 2018

Objectives

1. *Describe the purpose, specific aims, or objectives.*
2. *State the hypotheses to be tested.*

Purpose: The purpose of this randomized clinical trial (RCT) is to test the efficacy of a Resourcefulness Training intervention designed for 94 parent (male and female) caregivers of technology-dependent children on the parents' psychological and physical outcomes and on family outcomes at 6 weeks, 3 months, and 6 months post-intervention. Theoretical underpinnings of Resourcefulness Training posit that caregivers with greater resourcefulness will experience less stress and, as a result, will augment their caregiving capacity. This intervention involves the following components: 1) a face-to-face session for teaching social (help-seeking) and personal (self-help) resourcefulness skills **using a 32 minute video**, 2) ongoing access to video vignettes of parents of technology-dependent children describing the application of resourcefulness skills in daily life, 3) 4 weeks of skills' reinforcement using daily journal writing by the parents, and 4) weekly phone calls from the intervention nurse over 4 weeks after face-to-face intervention training. Booster sessions for the intervention group at 2 and 4 months post-intervention consist of a phone call and one week of journal writing. The Attention Control group will receive weekly phone calls for the first four weeks plus any usual care. In this exploratory stage of intervention work, we will evaluate the impact of the intervention on psychological and physical outcomes and family outcomes (family functioning) over time and whether changes in resourcefulness skills mediate these outcomes.

The specific aims of the study are to: Aim 1: Determine whether Resourcefulness Training versus Attention Control improves psychological (general mental health, depressive cognitions, depressive symptoms, appraised stress, burden) and physical outcomes (general physical health, chronic stress [hair cortisol]) and family outcomes (family functioning) over 6 months in parents of technology dependent children, after controlling for the parents' race/ethnicity, sex, family income, and children's functional status. Aim 2: Determine whether changes in psychological and physical outcomes andfamily outcomes are mediated by changes in parents' levels of resourcefulness (personal and social).

Background

1. *Describe the relevant prior experience and gaps in current knowledge describing how it will add to existing knowledge.*
2. *Describe any relevant preliminary data.*

Please add relevant references at the <u>end</u> of the protocol, not at the end of this section.

<u>Introduction/Background</u>

Caring for a child at home who is dependent on medical technologies such as mechanical ventilation, intravenous nutrition, feeding tubes or tracheostomies, can be a daunting task. Mothers, often the primary caregivers of technology-dependent children, not only manage the demanding care regimens and coordinate the frequent health care and therapy appointments, but must handle many other household responsibilities and perhaps outside employment. Past

research indicates that maintaining the mental health of caregivers and positive family functioning affect the chronically ill child's growth and development.[1] Toly[2] found that 39.2% of mothers caring for a technology-dependent child at home (n=103) scored ≥ 16 on the Center for Epidemiological Studies- Depression Scale (CES-D) indicating high risk for clinical depression. Furthermore, 34.9% of the variance in family functioning was explained primarily by level of depressive symptoms, underscoring the impact of such symptoms.[2] Empirical evidence indicates that resourcefulness training (RT) is an effective cognitive-behavioral intervention that directly contributes to a decrease in negative emotions and depressive cognitions and improved functioning and health[3-5]and it can be implemented on an individual basis in a variety of locales.

This pilot study will provide valuable experience in the development and testing of a RT intervention with mothers of technology-dependent children as well as provide necessary preliminary data regarding effect size for a larger, subsequent intervention study. The study results will also aid in any necessary intervention modifications based upon the feasibility, acceptability, and fidelity information gleaned from participants and interventionists.

Justification/Rationale/Significance of the Study

In controlled, experimental trials, RT was found to significantly improve resourcefulness,[3-5] adaptive functioning and life satisfaction[15] in elders. RT also improved negative emotions, functioning and depressive cognitions up to 12 weeks post intervention.[6] While past studies of RT have used a group teaching format/videoconferencing,[4] two current studies are examining the efficacy of RT using an in-person individual format including grandmothers raising grandchildren.[16] This format is based on research indicating stronger effects for individualized interventions[16]. Additionally, this study includes an opportunity to practice and reinforce RT skills taught using expressive writing (EW); personal journaling about specific events. EW has been found to significantly improve physical and psychological health and reduce negative emotions as well as health care visits.[17] While RT has not been tested in young caregivers, equivocal effectiveness is anticipated.

Although children with special health care needs comprise only 16.2% of all children under 18 years, they accounted for 45.5% of the medical expenditures in 2000 due to significantly more out-patient visits, hospitalization, and medications than other children.[18] Children who are technology dependent, while small in number, consume a large proportion of the health care dollars, yet little research has been done to examine how to help promote positive family functioning that will assist in better care for their child.

The study model is based on resourcefulness theory.[19-20] Major constructs in the model represent contextual factors, process regulators, resourcefulness (personal, social), and quality of life outcomes. RT is proposed to directly affect all model constructs except contextual factors as indicated by dashed lines. **Contextual factors** include mother's variables (age, race, income, education), child's variables (age, level of technology dependence, functional status) and caregiving situation (duration of care, amount of home health care nursing). **Process regulators** (depressive cognitions, depressive cognitions, burden, stress) include variables that mediate effects of contextual factors on resourcefulness. Depressive cognitions are thought patterns that

may lead to depression.[22] Assertions that cognitions influence resourcefulness has been validated in women caregivers.[19]

Resourcefulness is an "acquired repertoire of skills and behaviors necessary for the successful execution of self-control behavior."[19 p.26] These skills are learned throughout life by informal training or may be taught in cognitive behavioral programs and include the belief that one is able to cope effectively despite adversity.[19] Skills of self-instruction, problem-solving, belief in coping effectiveness are used to control the effects of disturbing feelings, thoughts and sensations on performance of daily tasks.[19] Zauszniewski's[20] model includes personal resourcefulness (self-help) and social resourcefulness (help-seeking) that are beneficial for maintaining healthy physical and psychological functioning across the lifespan. Resourcefulness training (RT) includes teaching positive self-talk, problem-solving and priority setting.[15]

Empirical evidence indicates that resourcefulness is a significant predictor of quality of life for non-caregivers/caregivers.[19, 23] **Parent outcomes** are conceptualized as absence of depressive symptoms, positive family functioning, better self-assessed health. **Depressive symptoms** include depressed mood and feelings of helplessness and hopelessness.[10] Greater resourcefulness is a significant predictor of a decreased level of depressive symptoms.[25] Conversely, less resourcefulness contributed to perceptions of worse family functioning in grandmothers raising grandchildren.[17] **Family functioning** is a parent's perception and level of satisfaction with relationships between the family and individuals as well as subsystems and the community. **Self-assessed health** is the mother's perception of her health and includes both physical and psychological well-being.[27] Based on the theoretical and empirical literature, the study model proposes that contextual factors, process regulators, and resourcefulness all directly affect quality of life outcomes.

Inclusion and Exclusion Criteria

1. *Describe how individuals will be screened for eligibility.*
2. *Describe the criteria that define who will be **included** in your final study sample.*

	Inclusion
1.	Parents who are at least 18 years of age
2.	Parents caring for a child age 16 years and younger at home who is technology-dependent (Group 1 mechanical ventilators; Group 2 intravenous nutrition/medication; Group 3 respiratory or nutritional support);
3.	Able to speak, write and understand English.
4.	

3. *Describe the criteria that define who will be **excluded** in your final study sample.*

	Exclusion
1.	Parents of children with cancer.
2.	
3.	
4.	

Number of Research Participants

1. *Indicate the target number of research participants to be accrued locally.*
2. *If this is a multi-site study, indicate the total number of research participants to be accrued across all sites.*

   For this study, 123 subjects are expected to be enrolled.

Vulnerable Populations

1. *Indicate specifically if you will include each of the following special populations by checking the appropriate box:*

   ☐ **Adults unable to consent**
   ☒ **Minors (infants, children, teenagers)**
   ☐ Wards of the state
   ☐ Foster Children
   ☒ **Pregnant Women**
   ☐ **Neonates**
   ☐ **Neonates of Uncertain Viability**
   ☐ **Employees of CWRU or UHHS**
   ☐ **Prisoners**
   ☐ **Illiterate Individuals**
   ☐ **Non-English Speaking**
   ☐ **University Students**

2. *If the research involves individuals that are included in a vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated.*

   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. While we will not be directly asking the children any questions we will be asking their parent to describe things such as what type of technological equipment they use and questions about their eating and sleeping. Therefore, we have a procedure for asking about the child's assent if they are 7 years or older.

3. *If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable rationale.*

   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.

Recruitment Methods

1. *Describe the source of the research participants.*
2. *Describe the methods that will be used to identify potential research participants.*

3. *Justify the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to?*
4. *Describe when, where, and how potential research participants will be recruited.*
5. *Describe materials that will be used to recruit research participants.*

Participant recruitment and enrollment: RB&C Specialty Clinics (Pulmonary, Gastroenterology, Trach/Vent, Comprehensive Care) and 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) and do prescreening for potential participants by checking pulmonology 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 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.

Discharge coordinators from RB&C 3, 5, and 6 who typically admit children who are discharged home dependent on technology will identify potential participants who meet eligibility criteria and ask if a study team member can speak with them about the study. If they agree, a study team member will talk with the parent and ask the best way to contact after the child is discharged home. Data collection would be completed following the child's discharge.

The RB&C Specialty Clinics (Pulmonary, Gastroenterology, Trach/Vent, Comprehensive Care) will identify names and contact information of patients meeting inclusion criteria. A letter describing the study and a request for the parent to contact the researcher will be sent by study staff to mothers. The letter also informs the parent that study staff will follow-up with him/her by telephone in about 1 week. This method of recruitment has been successful in the Principal Investigator's previous studies. An assent information letter for the child will

also be included with the letter sent to the mother. The parent is to give this letter to the child to read if he/she is over age 7 years and able to read it independently. If the child is over 7 years of age and is unable to read the letter independently, the mother will be asked to read it to the child. The parent will then obtain verbal assent from the child that he/she is in agreement to have the mother participate in the study. 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.

We will also recruit potential participants using Facebook and Twitter. 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. 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.

Participants who meet the inclusion criteria will be identified by the RB&C pulmonary, gastroenterology, trach/vent and comprehensive care clinics and invited to participate. A letter describing the study and a request for the parent to contact the researcher will be sent by study staff to these mothers. The letter also informs the parents that study staff will follow-up with him/her by telephone in about 1 week. This method of recruitment has been successful in the Principal Investigator’s previous studies. An assent information letter for the child will also be included with the letter sent to the parent. The parent is to give this letter to the child to read if he/she is over age 7 years and able to read it independently. If the child is over 7 years of age and is unable to read the letter independently, the parent will be asked to read it to the child. The parent will then obtain verbal assent from the child that he/she is in agreement to have the mother participate in the study. Potential participants will be contacted by telephone to assess eligibility and to determine if she is willing to participate in the study. Following this assessment and affirmation of the parent’s willingness to participate they will be queried as to the child’s receipt of the assent letter and confirm the child’s assent to have the mother participate in the study. 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. If the potential participant does not contact the research team in 1 week a phone call will be made to invite them to volunteer for the study.

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.

Potential participants will also be recruited using a Facebook page 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.

1. A Facebook page will be developed to post the flyer and increase awareness regarding the study. A "Friend" request will be sent to other parent caregiver organizations with Facebook sites likely to include eligible participants asking for permission to post the IRB approved study flyer on their Facebook page and let their members know about the study. The informational letter to be sent with the "Friend" request is attached.

2. 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:

@resourceTD needs your help to test a way to reduce stress in #parent #caregivers of technology-dependent children in Northeast Ohio!
@resourceTD 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!

Following this assessment and affirmation of the mother's willingness to participate the parent will be queried as to the child's receipt of the assent letter and confirm the child's assent to have the mother participate in the study. 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. If the potential participant does not contact the research team in 1 week, a phone call will be made to invite them to volunteer for the study.

An appointment will be made to meet with the potential participant at the time and place of their choosing (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. 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. No data collector that has clinic contact with the potential participant will engage in their recruitment so there is no undue influence to participate. Parents will be

assured that none of the data obtained will be communicated to any healthcare personnel at the outpatient clinic or hospital site. A study brochure will be given to participants.

Setting

1. *Describe the sites or locations where your research team will conduct the research.* We will conduct the research data collection at a private place of the parent's choosing such as their home, library. Our study office is located in the FPB School of Nursing, CWRU.

2. *Identify where your research team will identify and recruit potential research participants.* 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) and Family Learning Center. 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 2 weeks we will contact them to see if they are interested in participating. We will also be using UH EMR (Physician Portal, 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

3. *Identify the physical location where research procedures will be performed.* See above comments. Data collection- private place of the parent's choosing.

Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes describe:

- *Where the consent process will take place*
- *Any waiting period available between informing the prospective subject and obtaining the consent*
- *Any process to ensure ongoing consent*
- *The role of the individuals listed in the application as being involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the research participants' understanding*

Where consent take place: Private place of the parent's choosing.

Waiting period: The potential participant will have time between when they schedule the appointment and arriving at the appointment.
*Process to ensure ongoing consent***:** The participant ensures ongoing consent if they schedule and show up for data collection appointments.
Role of individuals listed on application involved in consent process: All listed on the application as obtaining consent will ask the potential participant if they would prefer to read the or to if they'd like the team member to go through the consent form with the participant. The team member would then answer any questions they may have about the study.
Time devoted to the consent process: 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.
Steps to minimize coercion or undue influence: No team member performing consent process will be provider of care for the parent, child. 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.
Steps to ensure 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.

Waiver or Alteration of Consent Process or Documentation (consent will not be obtained, written consent will not be documented)
Indicate which part of the consent process you are requesting be waived or altered:

- ☐ I will obtain consent, but not participant's signature
- ☒ I will obtain consent, but request a waiver for pre-screening purposes
- ☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception)
- ☐ I will not obtain consent, and I am requesting a full waiver of consent

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. *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**
   Describe how you will be documenting that a research participant has consented

   Be sure to upload a consent script or information sheet with your study protocol

Additional Considerations for Consent Process with Adults
Non English Speakers

- *If research participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Indicate the language that will be used by those obtaining consent.*

- *List the language(s) other than English that will be included.*

Above is Not Applicable

Adults Unable to Consent

- *Describe the process to determine whether an individual is capable of consent.*
- *List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child).*
    - *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research.*

Above is Not Applicable

- *Describe the process for assent of the research participants. Indicate whether:*
    - *Which subjects that are unable to consent will be required to give assent? If not all, explain why.*
    - *Describe whether assent of the research participants will be documented and the process to document assent.*

Above is Not Applicable

Research Participants Who Are Not Yet Adults (infants, children, teenagers)

1. *Will parental permission be obtained from:*

   ☐ *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child or*

   ☐ *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child*

   ☐ *Waiver of parental permission*

Above is Not Applicable

2. *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research.*

Above is Not Applicable

3. *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.* **Children who are 7 years of age or older. An assent information letter for the child will also be included with the letter sent to the parent. The parent is to give this letter to the child to read if he/she is over age 7 years and able to read it independently. If the child is over 7 years of age and is unable to read the letter independently, the parent will be asked to read it to the child. The parent will**

then obtain verbal assent from the child that he/she is in agreement to have the mother participate in the study

4. *When assent of children is obtained describe how it will be documented.*

Assent will be documented during the time scheduling takes place. Document along with scheduling notes in Project Manager's log.

Sharing of Results with Research Participants

Describe whether results (study results or individual subject results such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with the research participants or others (e.g. the subject's primary care physicians) and if so, describe how the results will be shared.

☒ Results will not be shared with research participants

Results will be shared after the study and the study analysis are complete by request only.

Study Design, Procedures and Timeline

1. *Describe and explain the study design.*

Research Design. A quasi-experimental RCT design with random assignment will be used to test the efficacy of a Resourcefulness Training (RT) intervention compared with an attention control group in mothers and fathers of technology-dependent children. All participants will receive a face-to-face visit from study staff for the T1 data collection. In addition, the intervention group will receive individually tailored RT web based instruction via an approximately 30 minute video that provides details on each of the 8 resourcefulness skills with short examples of application, instruction on journal writing to practice and reinforce use of resourcefulness skills, access to video tapes of parents describing application of resourcefulness skills in the care of their technology-dependent child. Parents will be asked to provide their email address so that we may send them invitation for access to the website that they may visit at any time to access the video tapes. Data will also be collected face-to-face at 3 months (T3) and 6 months (T4) post-intervention. At 6 weeks parents will be emailed a link to the REDCap survey for Time 2 data collection and contacted by phone for SF-12 survey with email reminders. Open-ended questions following their final data collection appointment will allow mothers/fathers to discuss feasibility, acceptability, and fidelity of this intervention and suggestions for potential modification of the intervention and follow up procedures.

For this study, 99 female participants and 24 male participants are expected to be enrolled that takes into account 10% attrition.

Measures/Instruments.

The **Depressive Cognition Scale** an 8-item scale (α =.75), will measure depressive thought patterns that may lead to depression.[8] Reponses on a 6-point scale range from strongly agree (5) to strongly disagree (0) with a score range 0-40. Items include depressive cognitions such as hopelessness and worthlessness; higher scores indicate more depressive cognitions.

The **Resourcefulness Scale,** a 28-item scale (α =.85), will assess both personal (16 items) and social (12 items) resourcefulness.[9] Responses on a 6-point scale range from extremely descriptive (5) to not descriptive (0) with a score range 0-140; higher scores indicate greater resourcefulness. Construct validity was assessed using confirmatory factor analysis.

The **CES-D Scale** will measure depressive symptoms.[10] The 20-item interval scale (α =.85), with responses ranging from rarely (0) to most or all of the time (3) is summed; higher scores indicate more depressive symptoms. A cut-off of 16 is used to identify those at high risk for clinical depression.

Medical Outcomes Short Form Health Survey (SF-12 v.2) is a 12-item scale that is a measure of perceived physical health status and mental health. It measures the following eight concepts: physical function, general health, bodily pain, role limitation due to physical health, bodily pain, vitality, social function, role limitation due to emotional problems and mental health. Two distinct component scores (physical, mental) are then derived. Median α for the two subscales is >.76.[27]

The **Feetham Family Functioning Survey (FFFS)**, a 25-item scale (α =.85), will assess family functioning.[12]Reponses on a 7-point likert scale range from little (1) to much (7) that asks (a) how much is there now? (b) how much should there be? This provides a discrepancy score; higher scores reflect greater the dissatisfaction with family functioning.[12]

The **Demographic Characteristics Questionnaire** includes questions about the child's age, mother's/father's age, education and race. Questions regarding additional covariates such as caregiving duration (years), home health care nursing hours per week and family income are also included. Mothers/fathers will also be asked if they are willing to be contacted in at a later date should future studies be conducted. If yes, mothers/fathers will complete the section of the demographic questionnaire with address, zip codes and names and contact information of 2 persons who might know there whereabouts should they move.

The **Functional Status II-Revised (FSII-R)** will assess the child's functional status.[13] The 14-item tool (α=.86) is administered in two parts. Part 1 asks parents about performance of the activity or behavior in the past two weeks with responses ranging from never/rarely (0) to almost always (2); Part 2 probes responses indicating poor function to determine if responses were due to illness. Higher scores indicate higher function.[13]

Level of Technology Dependency Questionnaire will be used to determine group assignment (Group 1 mechanical ventilators; Group 2 intravenous administration of nutritional substances/drugs; Group 3 respiratory/nutritional support equipment). Past studies of this population have used this rubric.[14]

Resourcefulness Skills Scale is an 8-item questionnaire (α=.78) that will assess the fidelity of the Resourcefulness Training (RT) intervention.[30] Participants are asked the frequency of use for each of the items taught in the RT intervention from never (0) to always (3). Higher scores indicate greater use of resourcefulness skills.[30]

Parent Inventory for Parents (PIP) is a 42-item scale (α=.80-.96) that assesses parenting stress (frequency, difficulty) of caring for a chronically ill child; higher scores indicates greater stress Construct validity was established by significant coreelations with state anxiety and general measures of parenting stress.

Chronic Stress will be measured by a hair cortisol sample.

Caregiver Burden will be measured using the Zarit Burden Interview-12 (α=.85-.89), a 12-item tool that assesses the burden people feel when taking care of another person; higher scores indicates higher burden.

Qualitative Assessment of Feasibility, Acceptability, and Fidelity of RT will be assessed by audio-recording **participant's responses** to: "Tell me what it was like for you to (a) do expressive writing and (b) apply RT?", "What parts were easiest/most challenging?", "What part of RT was most/least interesting?", "Did you learn all parts of RT?", "How can we enhance RT teaching/learning in the future?" "Any parts of the intervention (ie. teaching or intervention materials) or follow up you think we can modify to appeal more to male caregivers?" The **research team responses** will be assessed by analysis of journal entry responses to the following questions on at least a bimonthly basis: "What parts of teaching RT were easiest/most challenging?," Was any portion of the intervention omitted?," "Is the timing of data collection appropriate?," "What portion (if any) of the intervention needs to be modified?," "What challenges (if any) have there been with study recruitment?," "Has any group contamination been noted?," "Describe rate of and reasons for attrition." "What challenges have occurred with the follow-up data collection?"

Table 1: Study Tools and Measures

Variable	Measure (Appendix A)	Time of measure	Reliability in previous studies
Outcome Variables: Parent		**Enroll 6 Wk 3M 6M**	
Psychological and Physical Health	Medical Outcomes Short Form Health Survey (SF-12 version 2)	**X X X X**	α=.85-.93
Depressive Cognitions	Depressive Cognition Scale	**X X X X**	α=.75-.93
Depressive Symptoms	Center of Epidemiological Studies- Depression Scale (CES-D)	**X X X X**	α=.84-.93
Stress	Pediatric Inventory for Parents (PIP)-subjective Hair Cortisol-objective	**X X X X** **X X X**	α=.80-.96 Sensitivity/Specificity=100%
Burden	Zarit Burden Interview-12	**X X X X**	α=.85-.89
Outcome Variable: Family		**Enroll 6 Wk 3M 6M**	
Family Functioning	Feetham Family Functioning Survey	**X X X X**	α=.73-.83
Mediating Variable		**Enroll 6 Wk 3M 6M**	
Resourcefulness: Personal	Resourcefulness Scale (Personal Resourcefulness Subscale)	**X X X X**	α=.83
Resourcefulness: Social	Resourcefulness Scale (Social Resourcefulness Subscale)	**X X X X**	α=.79
Covariates		**Enroll 6 Wk 3M 6M**	
Parent: · Race/Ethnicity, Gender, Family Income	Enrollment form	**X**	IRR=1.0
Technology-Dependent Child: · Functional Status	Functional Status II-Revised	**X X X X**	α=.76-.80
Sample Characteristics		**Enroll 6 Wk 3M 6M**	
Parent: · Age, Marital Status, Duration of Tech. Dependent Child Caregiver Role · Education, Amount of Home Nursing Support Services, Lay Caregiving Assistance · Interpersonal Support	Enrollment form Enrollment form Interpersonal Support Evaluation List	**X** **X X X X** **X X X X**	IRR=1.0 IRR=1.0 α=.88-.90
Technology-Dependent Child:			

· Age · Type of Medical Technology Used	Enrollment form Technology Dependency Questionnaire	**X** **X**	**X**	**X**	**X**		IRR=1.0 NA

After confirming the child's assent and obtaining the participant's written informed consent, the participant will be assigned a code number. Mothers/fathers will be randomly assigned to one of two treatment conditions-Resourcefulness Training intervention or Attention Control using the Minim computerized method of random assignment based on parent gender, child's type of technology (mechanical ventilation or intravenous medication/nutrition, all others), race ethnicity (White non-Hispanic, all others). Data collection will take place in a private place of the mother's/father's choosing such as her/his home. The instruments should take about 50 minutes to complete at initial enrollment but thereafter it should take about 30 minutes (Table 1). After the participant has completed the self administered questionnaires, the interviewer will score the CES-D. If the total score of the CES-D exceeds the cutoff of 16 for depressive symptoms the participant will be notified and the information regarding mental health resources will be given-(see additional files). Following T1 data collection, mothers/fathers will receive either intervention or attention control protocol according to their random assignment. The RT intervention which includes instruction on maintaining a 28 day journal will take about 45-50 minutes to review with participants. At T4, one additional questionnaire, Resourcefulness Skills Scale, will be given to the Resourcefulness Training intervention group only to assess for intervention fidelity. Reminder post cards will be sent as needed. A $25 gift card will be given following completion of questionnaires at each of four time points. Following completion and submission of all questionnaires and the RT journals, participants will be interviewed via speaker phone to determine the feasibility, acceptability and fidelity of the intervention. Telephone interviews will take place at a time convenient for the participant and will be audio-recorded.
In order to aid in retention, participants will be mailed birthday cards on the parent's and child's birthdays as well as monthly postcards with an inspirational message and contact information for the study office.
The **RT intervention** group will be taught RT skills and mnemonic strategies (acronyms, practice) to facilitate recall of RT skills using a web based program that includes a video approximately 32 minutes long. The 8 letters in the acronym **RESOURCE** will be used to prompt recall: **R**ely on family/friends; **E**xchange ideas with others; **S**eek professionals or experts; **O**rganize daily activities; **U**se positive self-talk; **R**eframe the situation positively; **C**hange from usual reaction; **E**xplore new ideas. Practice of RT will occur through using a personal semi-structured journal (example in other study documents) to daily record which resourcefulness skills were used that day as well as one's thoughts and feelings related to specific situations in which the resourcefulness skills were used. As intervention reminder tools mothers/fathers will be given a laminated card to keep in their journal as well as a magnet to

place on their refrigerator with the above 8 letter acronym RESOURCE and reminder phrases as well as the PI's name, research study office email and telephone number (See Attachment). They will also be given a brochure with a summary of the intervention. The intervention nurse will also obtain the participant's email so that an invitation can be sent to access the study RT videos on Box.com. The RT intervention group will be asked to review their RT laminated card with the RESOURCE acronym each day prior to journaling and write about any RT skills used. To assist with adherence to daily journaling, the intervention nurse will make weekly calls for 4 weeks to query for questions; reminding them to write in their journals. Mothers/fathers will be encouraged to summarize the events for any days missed. Journals will be mailed back by participants in the self-addressed, stamped envelopes provided at 4 weeks after RT to monitor adherence and review for content. The intervention nurse will also describe the use of the RTvideo and the video tape vignettes (2-3 minutes each) as examples of resourcefulness skill application during care of their technology-dependent child.

Booster sessions of Resourcefulness Training 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. The sessions will be conducted in 8 to 10-minute telephone calls. The intervention nurse will record the parent's memory of skills learned, review skills that have been forgotten, determine whether he/she still has and uses the RESOURCE 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 RESOURCE 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 journaling as they did for the initial Resourcefulness Training intervention, using journal pages given in advance. We will phone them one week after each booster session (2-3 minutes) to inquire about their journaling and answer questions about application of resourcefulness skills. They will be asked to return their journals in a study-provided self-addressed, stamped envelope. To keep contact equitable control group participants will receive phone calls (about 5-10 minutes) from the study team at 2 and 4 months post-enrollment to ask how the participant and child have been doing since last contact and to remind them of upcoming appointments.

2. *Provide a description of all study-related **research procedures** being performed including procedures being performed to monitor research participants for safety or minimize risks.*

Minimal risk is involved with participation in this study. Physical discomforts might involve fatigue due to the length of time (about 50 minutes) needed to

answer the interview and study questions. Parents will be told that they may choose to take a break at any point during the interview. The amount of time required for participation in the study may also be viewed as an inconvenience. 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. Participants will be told that they may withdraw from the study at any time. The interviewer will be vigilant to assess the participant's discomfort. Participants experiencing considerable discomfort will be asked if they wish to stop the interview and will be given supportive assistance by the interviewer. The mother/father will then be given 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 cutoff of 16 on the Center for Epidemiological Studies (CES-D) measure she/he will be told of the findings and given an information sheet regarding accessing mental health care resources such as United Way First Help (phone 211) or the Cuyahoga County 24-Hour Mental Health Crisis Information and Referral Hotline (216-623-6888). Any participant noted to have a score of 23 or above on the CES-D 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 Mobile Crisis Team from the Cuyahoga County 24-Hour Mental Health Crisis, Information and Referral Hotline immediately. The risks and discomforts involved are reasonable because the risks are temporary and can be minimized by the above procedures. In addition, the discomfort is no more than what the participant might experience in her/his daily life.

3. *Describe:* **Procedures to decrease risk- See above**
   Drugs/Devices; Source Records- Not Applicable

   ☐ *Procedures performed to lessen the probability or magnitude of risks*

   ☐ *List all drugs and devices used in the research and the purpose of their use and their regulatory approval status (more detailed information is requested in the section on Drugs and Devices at the end of this document.)*

   ☐ *The source records, including medical or educational records, which will be used to collect data about subjects*
4. *Describe when research procedures will take place and the duration of an individual subject's participation in the study. Use of the descriptive table listing the study procedures that indicates the visit/week of the interventions below is encouraged.* **See above table and description.**

Radiation and Radioactive Substances

1. Does the research involve the use of radiation or radioactive substances?
   ☐ Yes ☒ No – leave rest of the section blank

   If yes, answer the following questions.
   Please note that you must receive Radiation Safety Committee (RSC) prior to IRB submission.
2. Is the radiation use only for the purposes of the research study (e.g. over and above standard of care)
   ☐ Yes ☐ No

3. Does the protocol use radionuclides?
   ☐ Yes ☐ No

4. Provide justification for the additional risk associated with the research radiation use.

ClinicalTrials.gov Information

Has this study been registered on ClinicalTrials.gov?

☒ Yes. Provide the following:

i. The ClinicalTrials.gov identifier: NCT03301831
ii. Investigator/sponsor responsible for registering: Valerie Toly

☐ No. Explain if there are plans to register or why registration is not required (i.e., the study is not NIH funded, registration is in process, or does not meet the definition of a clinical trial)

List of Data to be Collected

1. *Indicate what identifiers you will collect*
   ☒ Name
   ☒ Address
   ☒ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
   ☒ Telephone number
   ☐ Fax number
   ☒ Email address
   ☐ Social security number
   ☒ Medical record number
   ☐ Health plan beneficiary number
   ☐ Account number
   ☐ Certificate/license number

- ☐ Any vehicle or other device serial
- ☐ Device identifiers or serial numbers
- ☐ Web URL
- ☐ Internet protocol (IP) address
- ☐ Finger or voice prints
- ☐ Photographic images
- ☐ Other: Any characteristic that would uniquely identify the individual

2. *List all other data to be collected for the research study (e.g. laboratory values, physician notes, length of stay, etc.).*

Hair sample for cortisol level, audio recording with only subject ID number for exit interview regarding intervention for intervention group only. Questionnaires will be administered as well.

Data Analysis Plan

1. *Describe the data analysis plan, including any statistical procedures. Provide a power analysis if applicable.*
2. *If applicable, describe the primary and secondary study endpoints including safety endpoints.*

ANALYSIS. All data will be entered into UH REDCap and cleaned.We hypothesize that parents receiving the Resourcefulness Training intervention will have significant improvement in parental outcomes (psychological and physical) and family outcomes (family functioning) compared with parents in the Attention Control arm. We also hypothesize that resourcefulness will mediate the effect of the intervention on all study outcomes.

Preliminary Analyses. Exploratory data techniques will be used 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 four time points.

Primary Analyses.
Aims 1 & 2: Analysis of the monthly rate of change in each of the parent outcomes in each arm will be estimated via linear mixed models and fit using SAS PROC MIXED.108,109 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 also 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, sex and 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 the two arms.

To determine if resourcefulness mediates the effect of the resourcefulness intervention on parent outcomes, a model-based causal mediation model110,111 will be fit using separate generalized linear 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 resourcefulness intervention on maternal outcomes at 3 months into direct and indirect (or mediated) effects and will allow us to estimate the proportion of the total effect that is mediated. Variance estimates, and consequently 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 also estimate the mediated effect using measurements of the mediator and maternal outcome taken at other time points as well (e.g., total effect of resourcefulness intervention on parent outcomes at 6 months that are mediated by personal or social resourcefulness at 3 months).

To account for any multiple comparisons, a Bonferroni-corrected two-sided significance level will be applied to all analyses for all aims. Additionally, as with any study, we expect some level of missing data at each time point. To adjust for the missing data in all mixed-models analyses, we will use pattern-mixture models. This modeling approach will be applied 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 and family outcomes when data is missing not at random.

Secondary Analyses. To obtain more precise estimates of the intervention effect on the time point interval rate of change in each parent or family outcome, additional multivariable analyses will characterize and estimate the relationship between potential covariates at baseline and each outcome. For continuous variables that do not have 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 outcome will also be tested in each model by including an interaction between a pre-specified 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 25th, 50th, and 75th percentiles of a modifier that is measured on an interval scale.

Sensitivity analyses will also be applied to all mediation models described for the Primary Analysis to evaluate the assumption of sequential ignorability (e.g., no unmeasured confounders of the association between the mediator and each maternal outcome). As described by Imai et al,111 this analysis will assess how large an effect an unobserved confounder must have on both models to cause a non-significant mediated effect.

Confidentiality of Specimens and Banking

☐ I am not storing specimens in this research project – *please leave the rest of this section blank*

Describe:

☒ *The source of the specimens* ***Hair samples for cortisol level***

☒ *Where the specimens will be stored* ***Locked file cabinet in study office***

☒ *How long the specimens will be stored* ***Until final data collection then shipped together in one batch to lab for analysis***

☒ *How the specimens will be labeled* ***Each hair sample will be labeled with participant ID number and time point sample taken***

☒ *How the specimens will be accessed* ***Going into locked file cabinet***

☒ *Who will have access to the specimens* ***Members of the research team who have IRB approval.***

☒ *When and how will the specimens be destroyed* ***The specimens will be autoclaved and destroyed following processing by the lab.***

☒ *How will the specimens be transported (Please note if transporting specimens, a Material Transfer Agreement (MTA) is required).* ***The hair samples are wrapped in foil and enclosed in an envelope. All samples will be shipped next day air FedEx to the lab in a box.***

Describe:

☐ *The procedures to release specimens including:*

i. The process to request a release

ii. Approvals required for a release
iii. Who can obtain specimens
iv. The data to be provided with specimens, including if the data will be identifiable to others ***No data other than ID number and time point.***

☐ *For genomic data, please include an attestation of no master list and no attempt will be made to re-identify the specimens.*

Are you storing the specimen for future use for other research projects?

☐ Yes
☒ No

Confidentiality of Data

1. To maintain the confidentiality of the data:
   ☒ I will use a unique study identifier (not derived from the participants personal identifiers) to code individuals' data and I will store this ID log separate from study data.
   ☐ Other (please explain)

2. How are you storing your electronic data?
   ☐ UH Redcap
   ☒ CWRU Redcap
   ☒ Secure Research Environment (SRE)
   ☒ CWRU Box
   ☐ OnCore
   ☐ UH Secure Network Drive
   ☒ CWRU Secure Network Drive
   ☐ Other - List storage method and provide justification:

3. ☒ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following location:
   Location: FPB School of Nursing- Study Office

4. If sharing data, describe: **Not Applicable.**
   - *The exact data elements that will be shared*
   - *How data will be sent*

(Please note if sharing data, a Data Use Agreement (DUA) is required.

HIPAA Authorization

If you are going to be accessing PHI (Protected Health Information), indicate how HIPAA authorization will be obtained (check all that apply):

☒ HIPAA authorization is in the consent form
☒ Requesting a full or partial waiver of HIPAA for prescreening
☐ Requesting a full or partial waiver of HIPAA

1. *Describe why the study cannot be completed without the specified identifiable information.* ***We would not be able to contact the participants for initial enrollment or follow up data collection.***
2. *If the identifiable information will be used or disclosed by anyone other than the research team, please state who those individuals/entities are and provide justification for the disclosure.* ***Not applicable.***
3. *Describe how long identifiers will be kept for in relation to study length and data collection and analysis.* ***They will be kept until data collection and analysis is completed and manuscript writing is finished.***

☒ I assure that protected health information collected for purposes of this research study will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512

Risks to Research Participants

1. *List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.*

   Minimal risk is involved with participation in this study. Physical discomforts might involve fatigue due to the length of time (about 50 minutes) needed to answer the interview and study questions. Parents will be told that they may choose to take a break at any point during the interview. The amount of time required for participation in the study may also be viewed as an inconvenience. 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. Participants will be told that they may withdraw from the study at any time. The interviewer will be vigilant to assess the participant's discomfort. Participants experiencing considerable discomfort will be asked if they wish to stop the interview and will be given supportive assistance by the interviewer. The mother/father will then be given 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 cutoff of 16 on the Center for Epidemiological Studies (CES-D) measure she/he will be told of the findings and given an information sheet regarding accessing mental health care resources such as United Way First Help (phone 211) or the Cuyahoga County 24-Hour Mental Health Crisis Information and Referral Hotline (216-623-6888).

Any participant noted to have a score of 23 or above on the CES-D 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 Mobile Crisis Team from the Cuyahoga County 24-Hour Mental Health Crisis, Information and Referral Hotline immediately. The risks and discomforts involved are reasonable because the risks are temporary and can be minimized by the above procedures. In addition, the discomfort is no more than what the participant might experience in her/his daily life.

2. *If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable.*
3. *If applicable, indicate which procedures may have risks to an embryo or fetus should the research participant or their partner be or become pregnant.* ***Not applicable.***
4. *If applicable, describe the risks to others who are not research participants.* ***Not applicable.***
5. *Describe the availability of medical or psychological resources that research participants might need.* ***See above.***

Provisions to Protect the Privacy Interests of Research Participants

Describe the steps that will be taken to protect research participants' privacy interests. (consider issues such as physical space, proximity to other, and participant preferences)

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 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.

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.

A digital audio recording device will be used during parent interviews that might be regarded as an invasion of privacy. The reason for use of the audio recording device is to allow the data collector to focus on the interview and probes without the encumbrance of taking notes and risk missing essential portions of the parent's response. Using the recording device will therefore add

to the richness of the interview data for analysis. The participant's name will not be mentioned on the digital recording. The recording device and any memory cards will be kept in a locked filing cabinet when not in use.

Potential Benefit to Research Participants

1. *Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.*
2. *If no direct benefit, state the potential benefit to society or others. Do not list compensation.*

Participants may receive some benefit from the stress reducing methods used in this study (Resourcefulness Training, journal writing). The potential risk for emotional distress is minimal and reasonable given the potential benefit for reducing stress and improving quality of life. This study will benefit other families by aiding in our understanding of what methods help mothers/fathers reduce stress and promote optimal family functioning when they are caring for a technology-dependent child.

Withdrawal of Research Participants

1. *Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent.*
2. *Describe the procedures that will be followed when research participants withdraw or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.*

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 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 complete the final phone interview that describes challenges of the intervention, suggestions for modifications in the intervention and/or data collection procedures, and reasons for desire to withdraw from the intervention 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.

Alternatives to Participation

1. *Please list other available clinical treatments.*
2. *Please state if a subject could continue on standard of care therapy and what that might include.*
3. *If not a clinical trial you may state that the alternative is not to participate. If there is a viable alternative you must list it in the consent.*

The only alternative to participation is to choose not to participate. Potential participants will be told that choosing not to participate would not affect their child's health care in any way.

Costs to Research Participants

☒ There are no costs to research participants or their insurance companies – *please leave the rest of this section blank*

1. *If applicable, describe what costs the research participants will be responsible for because of participation in the research including but not limited to: transportation to study visits, parking for study visits, costs of procedures, lost, broken or stolen devices, costs of drugs or therapy, etc.*
2. *You must clearly state if insurance will be charged and who will be responsible if insurance does not pay.*
3. *List what research procedures and research interventions will be covered by this study.*

Research Participant Compensation

☐ There is no compensation for research participants – *please leave rest of this section blank*

1. *Describe the schedule, payment method and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amounts, t-shirts, devices, bags, swag, etc.)*
2. *Describe the schedule, payment method and payment total of any reimbursements that research participants will receive for participation in research (e.g., parking, mileage, meals, etc.)*

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 Amazon gift card at each of 4 time points following completion and return of the questionnaires. The total payment will be $100 over the study time if they complete all portions (4 data collection points) of the study.

Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

☐ Funding agency is providing some/all payment for injury
☐ Funding agency is providing no payment for injury
☒ Not applicable

Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. *Describe the Data and Safety Monitoring Plan for the proposed study. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol.*
2. *Is there a formal Data and Safety Monitoring Board/Committee? If yes, provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc.*

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

a. Monitoring Entity

A Safety Monitoring Committee (SMC) team will be comprised of "non-research team" members from the university community, including a bioethicist who is also a nurse (Dr. Barb Daly bjd4@case.edu), a statistician not involved with the project (Dr. Chris Burant cxb43@case.edu), and a doctorally prepared RN (Dr. Sara Douglas sld4@case.edu) with a specialty in caregiver research. Study team members will include Dr. Valerie Toly, PI, and Dr. Carol Musil, Co-I. Dr. Daly will chair the committee and be responsible to submit reports to the NINR within 2 weeks of the meeting. The committee members who are outside the study team will review data on the study as provided by Drs. Toly and Musil and conduct random auditing of the research records to assess study safety and regulatory compliance.

b. Data Safety Monitoring Committee

Twice annually throughout the project, 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. If concerns or problems are identified by the SMC, they will be

reported to the IRB and NINR/NIH via email by Dr. Toly and Dr. Daly, respectively, 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 NINR Officials within 2 weeks.

c. Adverse and Unanticipated Events

At the onset and across the duration of the study, all staff and Investigators will have instructional review of the nature and types of unanticipated and adverse events as described by the NINR and the CWRU IRB. As they occur, all unanticipated events and adverse events will immediately be reported to the PI who will report them to the IRB according the IRB protocol reporting procedures for both serious and non-serious adverse event and unanticipated problem reporting. These will be summarized in the twice annual reports to the SMC. Annual progress reports to the IRB and NINR/NIH will include a summary of the SMC's activities and findings as well as any adverse events regarding human subjects. Program Officials at NINR will be informed in a timely manner (3 business days) of unanticipated problems (e.g., a data breach) or unexpected serious adverse events that may be related to the study protocol or IRB-approved revisions to the study protocol that indicate a change in risk for participants.

Although this study is deemed as having minimal risk, we recognize that some unanticipated or adverse events may occur, which may vary in seriousness. As an example of a less serious event, if a participant learns the nature of the experimental condition (Resourcefulness Training) and calls to express disappointment, we will inform him/her before he/she completes the study that all participants who are in the comparison group will be given the opportunity to receive the Resourcefulness Training after completing the study. These situations will be noted and reported at the next SMC meeting.

Some participants may have personal situations that may cause them to contact our project staff for assistance. If parents contact us requiring assistance of any kind, we will note that and give them United Way's *First Call for Help* telephone number. The *First Call* service provides resources on various issues such as legal matters, housing, etc. We also will have a list of statewide and national agencies for making necessary referrals and can provide more specific resources if necessary. Experienced project staff, including the Investigators, will be available to talk with participants usually within 24 hours should they express distress, concern or request help for problems. These situations will be documented and reported to the IRB and to the SMC and reviewed as necessary for protocol implications. If parents have questions regarding the care of their children they will be referred to their child's healthcare provider.

For serious adverse events, the PI or Project Manager will report to the IRB, as per CWRU reporting requirements, within 3 business days, any serious adverse event that occurs, such as the death of a research subject, even if presumed to be unrelated to the study protocol.

d. Multi-site Study Compliance

This is not a multi-site study, however, all investigators and study staff will be instructed in the components of the data and safety and monitoring plan and reporting requirements.

e. Assessment of External Factors or Relevant Information

Annual assessments of new literature in the field that may have an impact on the safety of participants or on the ethics for the research study will be conducted by the graduate student research assistant under the oversight of the PI and Co-Is. The PI and Co-Is will evaluate this new information for its bearing on all aspects of this research project. This information and the team's analysis will be disseminated to the SMC at least annually, or sooner if important external factors or relevant information is identified that impacts subject safety or raises ethical concerns. In addition, at each committee meeting, SMC members also will be queried about new studies or ethical issues that they think should be discussed or reviewed, and these items put on the SMC meeting agenda.

f. Advanced Plans for Interim or Futility Analysis

This research project compares the psychological and physical outcomes of Resourcefulness Training against Attention Control in parents caring for technology-dependent children at home. The study investigators anticipate a medium effect size for these interventions; given this expectation and the low risk nature of the study, no formal "futility analysis" will be conducted. However, data summaries will be reviewed by the SMC every six months and interim analyses will be conducted as recommended by the SMC.

Drugs or Devices

☒ There are no drugs or devices being utilized in this research project – *please leave rest of this section blank*

1. *If the research involves drugs or device(s), describe your plans to store, handle, and administer those drugs or device(s) so that they will be used only on research participants and be used only by authorized investigators.*
2. *How will the drug(s) be dispensed (i.e., indicate the pharmacy that will be used)?*
3. *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), identify the holder of the IND/IDE/Abbreviated IDE*

Additional Information

If you have any additional information regarding your study not covered in the template, please include it here.

Community-Based Participatory Research

☒ This is not a community-based participatory research project – *please leave rest of this section blank*

If applicable, describe the involvement of the community in the design and conduct of the research.
Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) protects, the community participates fully in all aspects of the research process.

International information

☒ This is not an international study – *please leave rest of the section blank*

☐ We will be conducting this research at the following international sites:
1.

☐ We are recruiting participants outside of the US from the following locations:
1.

☐ We are sending data outside of the US to the following locations:
1.

☐ We are receiving data from outside of the US from the following locations:
1.

MULTI-SITE RESEARCH (when UH or CWRU is the IRB of Record)

Does this project have multiple sites?

☒ **Yes**

☐ **No**

The Cleveland Clinic Children's Hospital (Pulmonary, Gastroenterology, Neurology sections) are only inviting their patient's parents to participate in the study. If the parent is interested they complete a form giving their contact information that the CC team sends to us via secure email.

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site:

2. PI of relying site:
3. Name of IRB contact:
4. Phone number of IRB contact:
5. Email address of IRB contact:

Non-Local Recruitment Methods for Multi-Site Studies
If this is a multi-site study and research participants will be recruited by methods ***not under the control of the local site*** *(e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. *Describe when, where, and how potential research participants will be recruited.*
2. *Describe the methods that will be used to identify potential research participants.*
3. *Describe the materials that will be used to recruit research participants.*

Above Not Applicable.

Multi-Site Research Communication Plan (when you are the lead investigator)
Not applicable

If this is a multi-site study where you are the ***lead investigator****, describe the processes to ensure communication among sites including:*

- *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*
- *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*
- *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*
- *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*
- *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

If this is a multi-site study where you are the ***lead investigator,*** *describe the method for communicating to engaged participant sites:*

- *Problems*
- *Interim results*
- *The closure of the study*

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Please reference the Investigator Manual for local institutional requirements.