Protocol Cover/Title Page

Teaching Parents Reiki for Their Adolescents Receiving Palliative Care

NCT03896165

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Protocol Synopsis (one page)

Study Title: Teaching Parents Reiki for Their Adolescents Receiving Palliative Care

Study Design

PICOT:
P: Parents and adolescents receiving palliative care
I: Teaching parents Reiki for use in the home
C: None
O: Primary: The primary outcome for the proposed study is the feasibility and acceptability of teaching Reiki to parents of adolescents receiving palliative care. Secondary outcomes include: adolescent global health, pain interference, medication use, and stress measures of hair cortisol (chronic, long term) and alpha amylase (immediate, short term); and parent symptom profile (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance and ability to participate in social roles and activities), and stress measures of hair cortisol (chronic, long term) and alpha amylase (immediate, short term).
T: Nine weeks from consent through follow up

This intervention is easily implemented across a wide range of geographically dispersed settings. Reiki is a popular complementary health approach across the United States. There are Reiki practitioners in every state according to The International Center for Reiki Training,[1] the largest organization of Reiki practitioners in the country. With a tested protocol, manual, and training, this intervention could be taught to Reiki practitioners and then parents and other caregivers for a reasonably small cost.

Significance

Despite advances in the assessment and treatment of symptoms, including adolescents receiving palliative care, parents still report that their children suffer. Adolescents with life-threatening/life-limiting conditions, many of whom are developmentally delayed, experience many symptoms and have complex co-morbidities requiring medical management.[2–4] Many of these adolescents could benefit from complementary health approaches (CHAs) such as Reiki, a gentle light touch biofield energy therapy. Parents of adolescents receiving palliative care also experience high levels of stress.[5,6] Previous studies have shown that empowering parents in the care of their chronically ill child helps parents better cope with challenges.[7–9] Preliminary evidence showed that professionally-delivered Reiki is feasible for children and adolescents receiving palliative care at home.[10] The majority of parents in that study said they wished they could learn Reiki so they might provide this relaxing therapy in the moment it was needed rather than waiting for the next professional session.

Teaching parents Reiki has the potential to impact both the child and the parent. Studies with adults have found that professionally-delivered Reiki decreased pain, anxiety, and other symptoms.[11] Parents like to feel empowered in caring for their very ill children[11,14] and doing so may decrease parental stress and other symptoms.[13] The National Center for Complementary and Integrative Health (NCCIH) considers Reiki to be safe, although little scientific evidence exists about the effectiveness of this intervention.[14] The proposed study addresses NINR priorities of advancing symptom science to "develop [and] test … novel, scalable symptom management interventions, including CHAs, in real-world clinical settings to improve health outcomes and quality of life"[15(p.15)] and the science of compassion to improve palliative and end-of-life care through "developing, testing, and implementing personalized, culturally congruent, and evidence-based palliative and hospice interventions . . . that best address the needs of underserved, disadvantaged, and diverse populations across the care continuum."[15(p. 31)] A long-term bonus of teaching parents to deliver Reiki is that once learned, Reiki is highly scalable and costs nothing to use, an important potential overall cost savings over other CHAs.

Study Schema

See Appendix 2.

1 Background and Rationale

Despite advances in the assessment and treatment of symptoms, including pain in adolescents receiving palliative care, parents still report that their children suffer. Advances in medical science and care have led to a growing number of children living with life-limiting chronic conditions. Out of 83 million children under the age of 19,[16] an estimated 600,000 to 1,600,000[17] are living with life-threatening/life-limiting conditions and over 180,000 are considered "medically fragile."[18] These children require intense medical and nursing care in the home and often experience lengthy, recurrent hospital stays, accounting for about 26% of hospital days and 41% of hospital charges.[19] Adolescents with life-threatening/life-limiting conditions, many of whom are developmentally delayed, experience many symptoms and have complex co-morbidities requiring medical management.[2–4]

Many of these adolescents could benefit from complementary health approaches (CHAs) such as Reiki, a gentle light touch biofield energy therapy. Parents of adolescents receiving palliative care also experience high levels of stress.[5,6] Previous studies have shown that empowering parents in the care of their chronically ill child help parents better cope with challenges.[7–9] Some CHAs show promise for symptom management without side effects, such as sedation from additional medication, thereby permitting greater alertness and allowing more interaction with family and friends.[20,21] Preliminary evidence from the PI's pilot study showed that professionally-delivered Reiki is feasible for children and adolescents receiving palliative care at home.[10] The majority of parents said they wished they could learn Reiki so they might provide this relaxing therapy in the moment it was needed rather than waiting for the next professional session. One non-experimental program found that teaching parents Reiki was feasible and acceptable in the hospital. Parents who participated in two or more training sessions felt more confident providing Reiki.[12] During informal interviews, parents said they felt good at being an active participant in their child's care and that their child experienced increased comfort, relaxation, and decreased pain.[12]

Parents of disabled adolescents receiving palliative care often suffer from high caregiver burden and chronic stress, leading to co-morbidities and decreased QoL. A cross-sectional survey conducted in Europe examined stress in 818 parents caring for a child with cerebral palsy.[22] Results showed that 26% of mothers had very high stress. When the child had a communication or intellectual impairment or moderate-to-severe pain, parental stress was higher.[22] Khanna et al. examined psychological burden for 204 parents of children with serious chronic conditions.[23] This study found that 75% of parents reported depression, and 67% had anxiety. We are interested in exploring whether adding a skill (Reiki) aimed at decreasing symptoms in the adolescent will result in a decrease in symptoms and chronic stress for the parent.

Teaching parents Reiki has the potential to impact both the child and the parent. Studies with adults have found that professionally-delivered Reiki decreased pain, anxiety, and other symptoms.[11] Parents like to feel empowered in caring for their very ill children[11,14] and doing so may decrease parental stress and other symptoms.[13] Reiki is non-invasive and can therefore be used with anyone. The National Center for Complementary and Integrative Health (NCCIH) considers Reiki to be safe, although little scientific evidence exists about the effectiveness of Reiki.[14] The proposed study addresses NINR priorities of advancing symptom science to "develop [and] test … novel, scalable symptom management interventions, including CHAs, in real-world clinical settings to improve health outcomes and quality of life"[15(p.15)] and the science of compassion to improve palliative and end-of-life care through "developing, testing, and implementing personalized, culturally congruent, and evidence-based palliative and hospice interventions . . . that best address the needs of underserved, disadvantaged, and diverse populations across the care continuum."[15(p. 31)] A long-term bonus of teaching parents to deliver Reiki is that Reiki is highly scalable and once learned, costs nothing to use, an important potential overall cost savings over other CHAs.

2 Aims and Objectives

AIM 1. Establish the feasibility and acceptability of teaching parents Reiki in the home to use with their adolescent receiving palliative care.

AIM 2. Explore adolescents' and parents' stress response and symptom profile (i.e., physical function, anxiety, depression, fatigue, sleep, social roles, pain level, and biologic hair and saliva markers).

AIM 3. Explore parents' confidence in delivering Reiki and beliefs in their ability to help their adolescent.

We will achieve these aims by enrolling 12 community-dwelling adolescent-parent dyads receiving palliative care at home. Teaching parents Reiki is highly innovative and may provide a novel, easily scalable method of promoting self-management of symptoms.

3 Study Design

This study is a mixed methods quasi-experimental one group design.

Parents of hospitalized ill children have been successfully taught to do Reiki with their children. However, no study that we are aware of has taught parents of community-dwelling children or adolescents receiving palliative care, nor has any study taught parents of these adolescents in a prospective, scientific manner. As such, a one-group feasibility, acceptability study design is appropriate to examine teaching parents Reiki one-on-one in the home using a short teaching period and booster session. The design and sample size will achieve the goals of the study, including preliminary symptom outcome measures and parental feelings about learning Reiki and providing this intervention to their adolescents.

3.1 Study population

Adolescent-parent dyads will be recruited in three ways: (1) at an outpatient appointment with the palliative care team; (2) during an inpatient hospitalization; or (3) by mailing a letter, pamphlet, and opt-in/opt-out postcard or emailing a letter and pamphlet to the parent and follow-up with up to three phone calls or emails to introduce the study. For two parent households, parents will need to decide which parent provides at least some care for the adolescent and will perform the bulk of the Reiki sessions. The parent will provide written consent and the adolescent will provide written or verbal assent if able. If the adolescent is developmentally delayed he/she may not be asked to provide written assent/consent. The decision of documented assent/consent will be determined by the judgment of the parent in conjunction with the clinical judgment of the Palliative Care Center. Whenever developmentally appropriate, the adolescent's assent/consent should be solicited through simple explanations, questions, and cues and his/her refusal respected.

3.1.1 Eligibility criteria

Participants will include adolescent-parent dyads receiving care through a palliative care service. We are using the World Health Organization definition of adolescent of ages 10-19 years. We will refer to this age group as adolescent throughout this protocol. Dyads will be **included** if the adolescent: (1) is 10 to 19 years old; (2) understands English; (3) has a prognosis of at least 2 months; and (4) if the parent/legal guardian provides at least some care for the adolescent most days of the week and is able to read and write English at the 8th grade level. Dyads will be **excluded** if (1) either the adolescent or the parent are taking or have taken any form of corticosteroids within the last 30 days (affects the HCC levels), or (2) either the adolescent or the parent has less than one inch of hair. Dyads will also be **excluded** if the adolescent resides in an inpatient facility, is in foster care/custody, or if the dyad does not have reliable means of storing samples at or below 32 degrees Fahrenheit.

We intend to enroll participants regardless of sex, gender, or race. However, the sample size will be too small to analyze results based on these characteristics.

3.1.2 Enrollment Details

We will recruit parent-adolescent dyads who fit the inclusion/exclusion criteria. All adolescents will have a life-threatening or life-limiting illness and will be receiving palliative care. Some of the adolescents will be cognitively and/or developmentally delayed and will not be able to give assent to the study. Parents of these adolescents are very aware of their adolescent's moods and symptoms and will choose to consent or not for the study with the best interest of their adolescent in mind. Data will be collected either on paper or using an iPad, depending on the participant preference and/or internet availability. Data will be collected either face-to-face (in the home or during an outpatient visit) or by phone depending on data to be collected and participant preference.

3.2 Study measures and outcomes

Table 1: Measures and Timing

Variable (source) # = adolescent, * = parent	T0: Enrollment	T1: End of Intervention	T2: 4-week Follow up
Demographics#*	X		
PROMIS Pediatric Global Health 7+2 or Parent Proxy Global Health 7+2#	X	X	X
PROMIS Pediatric Pain Interference or Parent Proxy Pain Interference#	X	X	X
Parent: (physical and emotional) PROMIS 29 Symptom Profile*	X	X	X
Hair Sample Collection#*	X		X
Parent Experience of Providing Reiki*			X
Saliva collection#*	Pre/post 2 Reiki sessions per week during weeks 1-4		
Medication Log#	Completed during weeks 0-4		
Parent intervention Log*	Completed during weeks 1-4		

Demographic form (T0) basic demographic information on both parent and adolescent.

Patient Reported Outcomes Measurement Information System (PROMIS), sponsored by the NIH. *PROMIS Pediatric Pain Interference* or *PROMIS Parent Proxy SF Pain Interference*,[24,25] assesses how pain interferes with daily life for the adolescent. Well-validated measures show significant correlations between child and parent reports of pain.[26] We will use the *PROMIS Pediatric Global Health 7+2* measure to obtain an overall evaluation score of the adolescents' physical and mental health. Both self-report and parent proxy versions are valid and reliable.[27] Adult profile *PROMIS 29 Symptom Profile* (parent)[28] assesses seven domains (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance and ability to participate in social roles and activities).

Medication Log documenting all pain medications given one week prior to and during the intervention period.

Parent Intervention Log provided for parent record keeping. These logs will document Reiki session details, including the date, time, and length of session, interruptions to session, where the session took place, and parent comments and reactions (including adolescent reactions).

Hair collection and assay: Hair cortisol concentration (HCC) is a measure of chronic stress. A recent study found that the mean cortisol level assayed in 1 cm of hair was correlated ($r=0.61$, $p<0.01$) with the mean

salivary cortisol.[29] A four-week follow-up period was chosen in order to obtain an accurate measure of HCC to determine any change in stress during the intervention period. Approximately 10-75 mg of hair[30] is cut from the posterior vertex region of the scalp as close to the scalp as possible. The posterior vertex has the lowest variation in cortisol levels, and is the preferred area for sampling.[31] Co-I (Ford) will train the PI and Co-I (Tate) on hair collection. We will take one cut at the first home visit (T0) and another at the four-week follow-up home visit (T2). Assay: Each 1 cm of hair approximates the mean cortisol level over the prior 1 month.[32] Samples are assayed in duplicate and inter- and intra-assay coefficients of variation calculated. HCC levels are expressed in hair as pg/mg.

Saliva collection and assay: Salivary alpha amylase (sAA) is a non-invasive biomarker that detects immediate changes in autonomic nervous system response, signaling a change in level of stress.[33,34] Interventional studies have shown a decrease in sAA levels as a response to an intervention meant to stimulate relaxation.[35,36] *Collection*: The Salimetrics Drool Tube for adults will be used for saliva collection from the parents and cognitively aware adolescents. The SalivaBio Swab for infants will be used for the remaining adolescents to eliminate any choking hazards. Samples will be collected for both parent and adolescent pre and post two Reiki sessions per week for four weeks. *Storage*: The swab will be placed in a Swab Storage Tube. Tubes will be put into a sealable plastic bag marked as parent or adolescent, the date and time of collection, and put into the home freezer until the PI or other team member collects them at the follow up visit. Samples will be transported on dry ice to the lab, and frozen at -20C until processed. *Assay*: The saliva samples will be batch processed after thawing using the Salimetric Alpha Amylase assay following manufacturer's instructions. The amount of alpha-amylase activity present in the saliva sample is directly proportional to the increase in absorbance at 405 nm.

The primary outcome for the proposed study is the feasibility and acceptability of teaching Reiki to parents of adolescents receiving palliative care. Secondary outcomes include: adolescent global health, pain interference, medication use, and stress measures of hair cortisol (chronic, long term) and alpha amylase (immediate, short term); and parent symptom profile (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance and ability to participate in social roles and activities), and stress measures of hair cortisol (chronic, long term) and alpha amylase (immediate, short term).

Because Reiki has not been taught to parents of adolescents receiving palliative care at home, we will determine the feasibility and acceptability of this intervention through calculating the percentage of dyads approached to the total participants who consented to participate in the study as well as completed the study. We will also conduct qualitative interviews with parents to examine what they thought of the teaching protocol, the usefulness of Reiki for stress and other symptoms, as well as their thoughts on the study as a whole. Secondary outcomes will be collected in order to explore preliminary evidence on overall health and quality of life as well as medication use for the adolescents and overall quality of life and symptoms of the parent.

3.2.1 Study events description

Dyads will be in the study for a total of nine weeks from enrollment to the follow-up visit. Screening occurs at least weekly and prior to enrollment. Enrollment and initial study measure completion, including first hair sample collection from both parent and adolescent, will occur at the beginning of Week 0. Parents will fill out the Medication Log during Week 0 in order to have a baseline of pain and anxiety medications before study intervention begins. The parent will receive Reiki training, a poster with suggested hand positions and a commercially-available book about Reiki in the home on the first day of Week 1. A visit window is defined as a week (7days) -1/+3 days from the initial Reiki training. During Week 2 the parent will receive a Reiki booster session with a repeat of the training and may ask questions. The parent will administer at least 5 times per week for at least 10 minutes each session. During weeks 1-4, the parent will collect saliva samples for themselves and their adolescent before and after any two Reiki sessions as long as they are collected on two separate days. At the end of Week 4, measures will be repeated either in person or by phone. During Week 8, measures will be repeated, the second hair sample obtained from both parent and adolescent, and the parent will participate in a qualitative interview. The qualitative interview will be administered in person by trained OSU College of Nursing

study staff as part of the interview session. Interviews will be audio recorded using a hand-held audio recording device. Audio recordings will be transcribed verbatim. Audio recording is voluntary and participants can choose to not have their interview recorded and still be a part of the study. See Appendix 2 for schema.

3.2.2 Exposure/Outcome measures and instruments

The main data collection will occur during enrollment (T0), end of the intervention period, Week 4 (T1), and the follow up visit in Week 8 (T2). Parents will be instructed on how to collect and store alpha amylase saliva samples for themselves and their adolescent. Collection: The Salimetrics Drool Tube for adults will be used for saliva collection from the parents and cognitively aware adolescents. The SalivaBio Swab for infants will be used for the remaining adolescents to eliminate any choking hazards. Samples will be collected for both parent and adolescent pre and post any two Reiki sessions on two separate days per week for four weeks. Storage: The swab will be placed in a Swab Storage Tube. Tubes will be put into a sealable plastic bag marked as parent or adolescent, the date and time of collection, and put into the home freezer until the PI or other team member collects them at the follow up visit. Samples will be transported on dry ice to the lab, and frozen at -20C until processed.

3.2.3 Data management

Data will be collected using either paper measures or electronic measures via iPad per patient preference and/or internet availability. Data collected electronically will use Research Electronic Data Capture (REDCap) and entered by study staff into the study-specific electronic database for analysis. To minimize risks of disclosure of participants' personal information, the study site will ensure management and protection of materials and information in compliance with national, state and institutional guidelines for protection of confidentiality of health-related research information. Any paper measures will be checked for completeness during collection by the study team member collecting the data. The Medication Log and the Parent Intervention logs will be paper only. Study staff will collect a snapshot of the de-identified medication log and intervention log periodically in coordination with study visits. If the Medication Log is blank, parents will be asked if they have given any pain or anxiety medications during the previous period and have the parent fill out the log if needed. If the Intervention Log is blank or does not contain at least 5 entries for the previous week, parents will be asked about Reiki sessions and will fill out the log if needed. Data collected on paper will be scanned and emailed to the PI via secure email when each participating dyad has completed the follow-up visit. Data entered from paper measures will be entered into a database using double data entry and checking.

3.2.4 Compensation

Each family will be given a total of $50 incentive payments, a $20 gift card at the first visit (includes initial measures and hair sample collection) and a $30 gift card at the follow up visit (also includes measures and hair sample collection).

3.3 Interventions

This is a one-group feasibility study. There is only one intervention group. The Overall-Study PI and Local PI will recruit professional Reiki practitioners who are trained at Level 3 or Master Level and have prior experience working with families and children. A Reiki Master will perform the initial teaching and instruct the parent how to perform a simple 15-minute Reiki session. Parents will complete a return demonstration using light touch with their adolescent. The parent will receive an introductory book on Reiki, an informational article, and a poster showing hand positions for their reference as well as the intervention log to record sessions. The initial teaching session will take about 1.5 hours with breaks. The initial teaching session will be conducted by a Reiki Master and will mark the beginning of Week 1. A Reiki practitioner (Master or Level 3) will provide a shorter "booster" session the following week to review techniques with the parent and answer questions. This session will last 45 minutes with breaks. The "booster" session will count as one day for that week. Parents will be asked

to complete a minimum of 15 minutes of Reiki with their adolescent at least five days per week for the four-week intervention period. Parents will receive a phone call from the research coordinator once per week during weeks three and four to check in with them and ask if they have any questions or problems with the intervention and will refer to a Reiki practitioner if needed.

4 Statistics and Data Handling

4.1 Statistical considerations

Primary outcomes (Aims 1): Feasibility will be examined by computing the proportion of approached subjects enrolled in the study, the proportion of subjects who complete Reiki training, and the proportion of enrolled subjects' who completed data collection. Qualitative data will be analyzed using a basic qualitative descriptive approach. Qualitative data (audio recorded interviews and field notes) will be transcribed verbatim, checked for accuracy, imported into Atlas.TI[37] for data management, and analyzed.[38] Portions of text are labeled or coded with terms that are descriptive of the user opinions and observations. Codes will be identified and defined in an iterative process by investigators independently coding the data and arriving at agreement in discussion/review. Codes are sorted and categorized into themes, which will be discussed in research meetings. We will use mixed methods to triangulate the qualitative and quantitative data to produce a more accurate picture of parental beliefs and experiences. These results will be used to refine procedures for future, larger studies. Qualitative results will be triangulated with quantitative results to answer questions of feasibility. Qualitative results will also be examined to explore the parents' confidence in delivering Reiki and beliefs in their ability to help their adolescent (Aim 3).

Secondary outcomes (Aim 2): Descriptive statistics will be used to check data distribution, identify outliers, examine the balance in baseline measurements, and report outcome measures (e.g. pain) at each time point. Trend plot will be used to visualize the trend of change over time. Pair-wise comparisons will be conducted to test the difference in the change in outcome measures (T0 versus T1, T1 versus T2, T0 versus T2) using two sample t-tests. We will not adjust for multiple comparisons to avoid further reduction of power. Mixed effect modeling for repeated measures will be used to examine the trajectories of treatment effect over time, adjusting for within-patient clustering from repeated measures and possible confounders.

4.1.1 Sample size

We will enroll 12 adolescent-parent dyads in order to achieve study objectives. The emphasis is on Aims 1 and 3, the feasibility and acceptability of the study as well as the parents' feelings about learning Reiki and their ability to help their adolescents. These aims will inform future study protocols. Aim 2 is exploring both parent and adolescent stress, symptoms, and overall quality of life. We are also testing data collection of hair and saliva in this population of adolescents receiving palliative care in the home. The preliminary results from the primary and secondary outcomes will inform the sample size of the next planned study, a two-group randomized controlled trial.

4.2 Management of data

4.2.1 Source documents [Site data management]

Source documents are the original records of participant information. The ICH-GCP guidelines define source documents as "original documents, data, and records." Source documents may include study-specific Data Collection Tools (DCTs). DCTs are instruments/tools used to collect/document the requested data at each of the sites involved in the project. The DCTs contain those variables listed in this protocol. Examples of DCTs may include medication logs, Reiki log, research files, surveys and specific research worksheets used to

document key research data elements. Consent forms (if applicable) and an enrollment log are kept at the sites to know which participants are being followed and to ensure accurate enrollment and comply with local IRB regulations. Source documents/DCTs remain at the site of collection.

4.2.2 Data capture [Data management]

Study site personnel will complete screening, enrollment, and make sure initial measures are complete. Site personnel will scan and email completed paper forms to the Overall PI via secure email transmission for double data entry or will enter data collected via research electronic data capture (REDCap). Any paper/scanned data will be entered into SPSS by the PIs undergraduate students who have been trained in double data entry and data checking.

As part of the NIH data sharing directive, de-identified data from this study will be transferred to the PCRC Data Repository located at the University of Colorado.

4.2.3 Record retention

- Any study records (including DCTs, etc.) will be retained in the site's research record for 10 years after the study is completed in accordance with Good Clinical Practice guidelines. At that time the research information will be destroyed by each site's research document destruction rules/regulations.
- Any research information already included in medical records will be kept indefinitely.
- The de-identified data that are collected and entered will remain in the PCRC Data Repository indefinitely.

4.2.4 Data sharing [REQUIRED LANGUAGE]

De-identified study data from this study will be transferred to the PCRC Data Repository located at the University of Colorado. The PCRC fully supports the Final NIH Statement on Sharing Research Data and will provide assistance to all investigators and personnel for compliance. Consistent with OMB Circular A-110 and subsequent NIH Grants Policy Statements, the PCRC will provide access to all de-identified data collected as part of PCRC-supported investigations, insofar as access is consistent with IRB/CHR rules, local, state, and Federal laws and regulations, and the HIPAA Privacy Rule.

5 Ethics and Dissemination

5.1 Ethics and regulatory compliance

We will submit this protocol and supporting documents (i.e., measures, consent) to the IRBs of Ohio State University (OSU) and Children's Hospital. OSU will cede control of the study to Children's Hospital IRB as the IRB of record per previous studies conducted at the same site with the same study team. We will seek additional language required by the PCRC for IRB applications and consent forms as well as advice from PCRC experts after funding.

5.2 Confidentiality

Every effort will be taken to ensure the confidentiality of study participants and their data. Only IRB-approved study team members who have completed human subjects research training will have access to study data. All study data, with the exception of consent forms, will be identified by a code number only. Consent forms and the list linking study participant names and code numbers will be kept in a locked drawer in a locked office separate from other study data. Participants will be referred to by code number only. All reasonable effort will be made to maintain participant confidentiality.

5.3 Data security

The Ohio State University (OSU) College of Nursing has secure electronic data servers that are password protected and behind firewalls. All electronic data will be stored on these secure servers. Additionally, data sent electronically will be identified by code number only. Paper data, including consent forms, will be stored onsite. Consent forms and the list linking names and code numbers will be stored separately from other data. Audio recordings from the interview will be recorded using hand-held audio recording devices and the files transferred to password protected computers at OSU. These audio files will be identified with a subject ID only. Files are saved on the OSU College of Nursing server, which is password protected, regularly backed up, and only accessible by authorized study team members. Once the files are saved onto the computer, the file will be deleted from the recording device. Files may be kept on the server for up to 5 years. Only study personnel will have access to either paper or electronic data.

6 Safety Considerations

6.1 Risks

The risk of participating in this study are minimal. Reiki is non-invasive and can therefore be used with anyone. NCCIH considers Reiki to be safe although little scientific evidence exists about its effectiveness.[14] There is the possibility that either the parent or adolescent may become uncomfortable during the Reiki session. If this happens, they should either take a break or change positions to be more comfortable. There is a risk for becoming tired or having pain due to the adolescent's illness during the Reiki session. If either of these happens, the dyad should take a break and/or change positions to one that is more comfortable. Some of the data collection may be uncomfortable or inconvenient for the parent and/or adolescent. The hair sample collection may cause a slight physical discomfort due to the gentle pull on the hair before cutting and may cause social discomfort if the parent or adolescent feels as though the small bare spot on the scalp where the hair was clipped may show. Any study personnel who will be collecting hair will be trained to perform the sample cut gently and in a spot not likely to show. Collecting the saliva samples may be inconvenient for the parent as two samples must be collected (pre and post) for both the parent and adolescent (four samples total each time) twice per week for four weeks and stored in the home freezer. We will provide pre-labeled sample tubes and baggies so that the parent only has to add the date to each baggie in order to decrease the inconvenience as much as possible.

Adverse Events. All adverse events (AEs) and serious adverse events (SAEs) will be tracked, documented, and reviewed. In one systematic review evaluating the efficacy of Reiki, nine randomized control trials reported no adverse events.[49] It is anticipated that AEs in this study will be minimal. However, for the purpose of this study, AEs will be defined as clinically significant mental status changes, or any other unusual symptom or event (e.g. significant pain, a fall) that occur during the time frame of each Reiki session. An SAE will be defined as any untoward medical occurrence that results in death, is life threatening, results in hospitalization, or results in persistent or significant disability. Parent participants will be instructed to call the research coordinator for the study to report any adverse or unusual events. Parents will be instructed to call 911 in the event of a medical emergency and report the emergency to the research coordinator or the palliative care on-call medical provider (physician or nurse practitioner) when they are able. In either case, the research coordinator will consult with one of the palliative care physicians or nurse practitioners immediately in the case of an SAE or within 24 hours of an AE. The PI of the study will be notified of all AEs and SAEs immediately via email for AEs and text message and email for SAEs. All AEs and SAEs will be reported to the IRB in a timely manner.

6.2 Benefits

The adolescent and/or parent may experience feelings of relaxation and/or decreased stress.

6.3 Monitoring

A. Study monitoring.

Because this is a small, one-site, low-risk pilot study, the PI will be responsible for the ongoing evaluation of the progress of the proposed research study. The overall PI and local PI will ensure that all eligibility criteria and consent requirements are met prior to a participant's participation and that all study procedures and AE reporting occur according to the IRB-approved protocol. The Ohio State University College of Nursing has created a Safety Monitoring Committee (SMC). This group will meet quarterly once recruitment has begun to review the study and any reports of untoward events and to monitor their resolution. Minutes will be kept of all meetings and following SMC meetings, the results of the meeting (meeting minutes) concerning possible negative side effects will be documented and sent to the Overall Study PI, Local PI, and the IRB. The local PI's IRB will advise and monitor the design and implementation of all safety monitoring and risk management procedures.

B. Procedures:

1) Monitoring study safety to include monitoring schedule, and auditing selected cases for compliance with IRB requirements, conformance with informed consent requirements, verification of source documents, and investigator compliance.

   Monitoring of study safety will occur monthly. Monitoring will begin with the first participant recruited. To ensure reliability of data entry, the Overall study PI will review a random sample of cases and compare the results with the information recorded in the database to monitor for compliance with IRB requirements. The Overall study PI will look at consent forms, data storage, and correct entries. An acceptable error rate is less than 3%, i.e., 3 per 100 entries. If error rate is more than 3%, the Overall study PI and a second member of the study team will recheck all data.

   Quality assurance reports will be prepared on a monthly basis by the Overall study PI and reviewed by Local PI. The reports will inform about missing, invalid, or inconsistent data on selected key variables such as age, sex, or diagnoses. The statistician on the project will oversee preparation of the reports. The reports will contain a summary of monthly accrual and cumulative accrual, a summary of key characteristics of the study participants, a summary of the completeness and quality of data.

   Quality assurance will involve engaging in good data management activities. Procedures that include checking the integrity of data storage and examining frequency distributions to look for data anomalies.

2) Minimizing research-associated risk: This study poses minimal risk to participants.

   Consent Procedures. Local PI, a research coordinator or another member of the study team will introduce the study to the adolescent and parent. Recruitment methods used by this palliative care center for previous studies will be used; these include approaching potential participants during regular clinic visits or mailing study information followed by up to three phone calls. If the study is introduced in the clinic, a member of the study team will introduce the study, and if the adolescent and parent are interested, a research coordinator will give more details about the study, go over the

consent form, answer any and all questions. If by mail, interested participants who meet criteria will call the palliative care center and the research coordinator will mail a packet with the consent form and study information and will schedule a phone call to discuss the study. The research coordinator will meet with the parent and adolescent either in the clinic or in the home to go over the consent form. Any and all questions will be answered before the parent gives written consent and the adolescent gives written assent, or consent if age 18 or over, if able. Adolescent-parent dyads that meet eligibility criteria and give appropriate consent will be able to participate in the study. To protect participant confidentiality, the research coordinator will discuss consent in a private room at in the clinic, hospital room, or patient's home. To prevent undue coercion, potential participants will be instructed that participation is completely voluntary, that their decision to participate will not affect their treatment, and that they may discontinue their participation in the study at any time. If the potential subject refuses to participate, there will be no further recruitment efforts but the subject will be asked about their reasons for refusal.

Risk of measures: It is possible that the adolescent or parent may become fatigued while completing consent or baseline measures that they may become fatigued. Participant burden was considered very carefully due to the nature of this study. Study measures to address the constructs were carefully chosen to minimize undue burden or fatigue.

Fatigue. To minimize fatigue, the adolescent and parent will be offered breaks during the study procedures. Participants may choose to discontinue any procedure at any time for any reason. If at any point the adolescent or parent becomes fatigued or the adolescent requires attention, we will either take a break or stop altogether depending on the preference of the adolescent or parent.

3) Protecting the confidentiality of participant data:

Risk of breach of confidentiality: There is a possibility of risk of breach of confidentiality of protected health information. The Overall study PI and the Local PI will take all necessary steps to ensure that this does not happen. All participants will be assigned an ID code upon entry into the study. All records relating to the participant's involvement in this research study will be stored securely within a locked office. Participant identities on these records are indicated by an ID code rather than by a name, and the file linking these ID codes with their identity are kept separate from the research records. Screening and enrollment logs will be kept securely password-protected on the server and de-identified when shared with Overall PI. Only the research coordinators will have the information to link the special ID codes to the participant's names. The master list will be kept in a password protected file on the protected server. No information will be used in subsequent publications that would identify individual participants.

This study does not involve evaluating drugs or devices.

Adequacy of Protection Against Risks: Efforts will be taken to minimize the risk to breach of confidentiality of data and anonymity of the participants. All participants will be assigned a unique ID code number under which all data will be stored. Security of the data will be upheld through the use of password protection, encryption, and restricted access to users. Consent forms and a list of the match between participant names and code numbers will be retained securely in a locked office area.

C. Procedures for identifying, reviewing, and reporting AEs and unanticipated problems to the IRB, funding sources, and FDA (if applicable). If applicable, the type and number of events that would halt accrual and

would generate a review of eligibility, monitoring, assessments, intervention, and how the resumption of accrual would occur.

Throughout the study the Overall study PI and Local PI will be responsible for monitoring participants for adverse events. The following will be considered SAEs: patient death, attempted suicide, major depression, or breach of confidentiality. The following will be considered AEs: patient allegations of physical/mental injury during the study, patient allegation of inappropriate consenting or recruitment procedures. The Overall study PI and Local PI will review AEs and unanticipated problems within 24 hours of notification of the event. Unanticipated problems that are SAEs will be reported within one week of the investigator becoming aware of the problem. Any other unanticipated problems should be reported within two weeks of the investigator becoming aware of the problem. All fatal or serious/life threatening AE will be reported to the IRB in accordance with IRB policy. Non-serious AEs will be reported to the IRB at time of continuing review. AEs determined as anticipated problems involving risks to subjects or others will be reported to IRB at time of continuing review. The Overall study PI and Local PI will be informed by team members about any AEs or unanticipated problems immediately. If protocol changes are needed, the research coordinator, with Overall study PI and Local PI approval, will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval unless necessary to eliminate apparent immediate hazards to the participants.

At each meeting of the SMC during the conduct of the trial, the SMC will make a recommendation to the Overall study PI to continue or to terminate the trial. This recommendation will be based on safety considerations. The Overall study PI is responsible with the SMC for safeguarding the interests of participants and for the conduct of the trial. The Overall study PI will be responsible for deciding whether to continue or to stop the trial based on the SMC recommendations.

D. For multi-site studies, procedures to ensure compliance with the monitoring plan and reporting requirements across study sites.

This is a single site study.

E. An assessment of external factors or relevant information (i.e., developments in the literature, results of related studies) that may have an impact of the safety of participants or on the ethics for the research study.

The Overall study PI will be responsible for reviewing the literature monthly and reviewing with Local PI and inform the study team of any new developments related to the study that may have impact on the safety of participants or the ethics for the research study.

F. The advanced plans for interim and/or futility analysis.

An interim analysis will occur at six months after study initiation to determine whether enrollment is adequate or if a revision in recruitment strategies is needed and/or if the study appears to be futile (no participants recruited during six months of active recruitment). The Overall study PI together with Local PI will determine if early closure is justified if anticipated accruals cannot meet stated study goals.

G. Description of how often monitoring entity meets, who will record proceedings, what group(s) receives SMC reports, and time period for completing reports should be specified.

The Overall study PI, and Local PI and study staff will meet every two weeks either in person or by phone. The research coordinator will document meeting proceedings. The SMC will meet quarterly.

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Appendices

Appendix 1: Study Glossary

Term	Definition
AE	Adverse event
CHA	Complementary Health Approach
CI	Confidence interval
DCT	Data collection tools
HIPAA	Health Insurance Portability and Accountability Act of 1996
IRB	Institutional Review Board
NCCIH	National Center for Complementary and Integrative Health
NIH	National Institutes of Health
OSU	The Ohio State University
PCRC	Palliative Care Research Cooperative Group
PROMIS	Patient Reported Outcomes Measurement Information System
PTES	Perceived Treatment Efficacy Scale
PI	Principal Investigator
QOL	Quality of life
RCT	Randomized controlled trial
SAE	Serious adverse event
T0	Enrollment
T1	Week 4
T2	Week 8

Appendix 2: Study Schema

	STUDY PERIOD						
# = adolescent * = parent	Screening / Enrollment	Intervention and Follow up Period					
TIMEPOINT	(T0)	Week 0	Week 1	Week 2	Week 3	Week 4 (T1)	Week 8 (T2)
Eligibility screening #*	X						
ENROLLMENT							
Informed consent/assent #*	X						
INTERVENTION							
Initial Reiki teaching			X				
Reiki teaching booster session				X			
ASSESSMENTS							
Demographics #*	X						
PROMIS Global Health 7+2 #	X					X	X
PROMIS Pain Interference #	X					X	X
PROMIS 29 Symptom Profile *	X					X	X
Hair Sample Collection #*	X						X
Alpha Amylase #*			X*2	X*2	X*2	X*2	
Medication Log #		X	X	X	X	X	
Qualitative Interview *							X

Appendix 3: Measures

Demographic Data Form **ID # _____**

Adolescent:

Where was the adolescent consented: Inpatient / outpatient clinic / home / other (circle one)

Has the adolescent been hospitalized in the last month? Y/N (circle one)

If yes, discharge date: _____

Age in years: _____ **Birthdate** _____

Sex:

☐ Unknown ☐ Male ☐ Female ☐ Not specified/Decline to answer

Race:

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Pacific Islander
☐ White
☐ Unknown

Ethnicity:

☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Religion:

☐ Amish
☐ Buddhist
☐ Hindu
☐ Muslim
☐ Spiritual but not religious
☐ Jewish
☐ Catholic
☐ Protestant/Christian*
(*includes Baptist, Presbyterian, Methodist, Lutheran, Episcopalian, Church of Christ, Pentecostal/Foursquare, Christian Science, Quaker, Unitarian, etc.)
☐ None
☐ Other: _____
☐ Decline to Answer

Primary diagnosis that resulted in palliative or hospice referral

_____

Is the child developmentally delayed? Yes _____No _____

(as defined by parent report & PPC provider opinion)

If yes, Diagnosis: _____ ICD-10 _____

Is the adolescent receiving palliative care? Yes _____ No _____

Date referred to palliative care: _____/_____/_____

Is the adolescent receiving hospice care? Yes _____ No _____

Where is care provided: _____

Date referred to hospice care: _____/_____/_____

Parent/Legal Guardian:

Age _____ Sex _____

Race:

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Pacific Islander
- ☐ White
- ☐ Unknown

Ethnicity:

☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Current Marital Status:

- ☐ Single
- ☐ Married
- ☐ Divorced
- ☐ Widowed
- ☐ Living with romantic partner
- ☐ Decline to answer

Employment:

- ☐ Part Time
- ☐ Full Time
- ☐ Seasonal/occasional
- ☐ Unemployed
- ☐ Family Medical Leave
- ☐ Homemaker
- ☐ Retired
- ☐ Decline to answer

Educational Level:

- ☐ Less than high school
- ☐ High school
- ☐ Some college
- ☐ Associates Degree
- ☐ Bachelor's Degree
- ☐ Master's Degree
- ☐ Doctoral Degree
- ☐ Decline to answer

Total number of people living in the household: _____

Total Family Income (yearly):

- ☐ < $10,000
- ☐ $10,000-19,999
- ☐ $20,000-39,999
- ☐ $40,000-59,999
- ☐ $60,000-79,999
- ☐ >$80,000
- ☐ Decline to answer

Religion:

- ☐ Amish
- ☐ Buddhist
- ☐ Hindu
- ☐ Muslim
- ☐ Spiritual but not religious
- ☐ Jewish
- ☐ Catholic
- ☐ Protestant/Christian*

(*includes Baptist, Presbyterian, Methodist, Lutheran, Episcopalian, Church of Christ, Pentecostal/Foursquare, Christian Science, Quaker, Unitarian, etc.)

- ☐ None
- ☐ Other: _____
- ☐ Decline to Answer

Pediatric Global Health 7+2

Please respond to each question or statement by marking one box per row.

		Excellent	Very Good	Good	Fair	Poor
Global01R1	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02R1	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03R1	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04R1	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Never	Rarely	Sometimes	Often	Always
PedGlobal2R1	How often do you feel really sad?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Always	Often	Sometimes	Rarely	Never
PedGlobal5R1	How often do you have fun with friends?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PedGlobal6R1	How often do your parents listen to your ideas?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Never	Almost Never	Sometimes	Often	Almost Always
2876R1r	I got tired easily	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3793R1r	I had trouble sleeping when I had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Parent Proxy Global Health 7+2

Please respond to each question or statement by marking one box per row.

		Excellent	Very Good	Good	Fair	Poor
Global01_PXR1	In general, would you say your child's health is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02_PXR1	In general, would you say your child's quality of life is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03_PXR1	In general, how would you rate your child's physical health?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04_PXR1	In general, how would you rate your child's mental health, including mood and ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Never	**Rarely**	**Sometimes**	**Often**	**Always**
PedGlobal2_PXR1	How often does your child feel really sad?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Always	**Often**	**Sometimes**	**Rarely**	**Never**
PedGlobal5_PXR1	How often does your child have fun with friends?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PedGlobal6_PXR1	How often does your child feel that you listen to his or her ideas?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days…					
		Never	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf4fatigue3r	My child got tired easily.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2pain5r	My child had trouble sleeping when he/she had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pediatric Pain Interference

Please respond to each item by marking one box per row.

	In the past 7 days.	Never	Almost Never	Sometimes	Often	Almost Always
1698bR1	I felt angry when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2035R1	I had trouble doing schoolwork when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3793R1	I had trouble sleeping when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9004	It was hard for me to pay attention when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2045R1	It was hard for me to run when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2049R1	It was hard for me to walk one block when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
1703R1	It was hard to have fun when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2180R1	It was hard to stay standing when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3582R1	I hurt a lot.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9009	I hurt all over my body.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2032R1	I missed school when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9007	It was hard for me to remember things when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
1701R1	It was hard to get along with other people when I had pain.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Pain Interference

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Never	Almost Never	Sometimes	Often	Almost Always
Pf2pain5	My child had trouble sleeping when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf3pain7	My child felt angry when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf2pain2	My child had trouble doing schoolwork when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf3pain2	It was hard for my child to pay attention when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf2pain4	It was hard for my child to run when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf1pain4	It was hard for my child to walk one block when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf3pain4	It was hard for my child to have fun when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf4pain6	It was hard for my child to stay standing when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf4pain2	It was hard for my child to remember things when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf4pain4	It was hard for my child to get along with other people when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf4pain1	My child hurt a lot	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf3pain6	My child hurt all over his/her body	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
Pf4pain5	My child missed school when he/she had pain	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
2	Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
3	Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
4	Are you able to run errands and shop?	☐	☐	☐	☐	☐
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐	☐	☐	☐	☐
6	I found it hard to focus on anything other than my anxiety	☐	☐	☐	☐	☐
7	My worries overwhelmed me	☐	☐	☐	☐	☐
8	I felt uneasy	☐	☐	☐	☐	☐
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐	☐	☐	☐	☐
10	I felt helpless	☐	☐	☐	☐	☐
11	I felt depressed	☐	☐	☐	☐	☐
12	I felt hopeless	☐	☐	☐	☐	☐
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐	☐	☐	☐	☐
14	I have trouble starting things because I am tired	☐	☐	☐	☐	☐

PROMIS–29 Profile v2.0

	Fatigue **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
15	How run-down did you feel on average? ...	☐	☐	☐	☐	☐
16	How fatigued were you on average?	☐	☐	☐	☐	☐
	Sleep Disturbance **In the past 7 days…**	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
17	My sleep quality was.....	☐	☐	☐	☐	☐
	In the past 7 days…	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
18	My sleep was refreshing.....	☐	☐	☐	☐	☐
19	I had a problem with my sleep	☐	☐	☐	☐	☐
20	I had difficulty falling asleep	☐	☐	☐	☐	☐
	Ability to Participate in Social Roles and Activities	**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
21	I have trouble doing all of my regular leisure activities with others	☐	☐	☐	☐	☐
22	I have trouble doing all of the family activities that I want to do	☐	☐	☐	☐	☐
23	I have trouble doing all of my usual work (include work at home)	☐	☐	☐	☐	☐
24	I have trouble doing all of the activities with friends that I want to do	☐	☐	☐	☐	☐
	Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
25	How much did pain interfere with your day to day activities?	☐	☐	☐	☐	☐
26	How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
27	How much did pain interfere with your ability to participate in social activities? .	☐	☐	☐	☐	☐
28	How much did pain interfere with your household chores?	☐	☐	☐	☐	☐

PROMIS–29 Profile v2.0

Pain Intensity

In the past 7 days…

29	How would you rate your pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst imaginable pain**

INTERVIEW GUIDE

Teaching Parents Reiki for Their Adolescents Receiving Palliative Care

Interviews with parents can take place in a setting of their choosing. Assure that the risk for interruptions is minimized.

Introductory Comments:
We value your opinions as parents who have been engaged in symptom management with your child. We'd like to obtain some feedback about using REIKI therapy to help with those symptoms. All opinions and information shared here will be confidential and your participation is anonymous. We don't share your names or your opinions by name or attach any identifying information to the transcript of this session. I will be recording this session if it's OK with you. This is just to make sure I get an accurate record of your answers. We will listen to the recording and transcribe the words into text on the computer. No one will have access to your responses except study personnel. Do we have your permission to proceed with the recording?

I have a series of questions I want to cover and these are open-ended questions so think of this more like a conversation than a questionnaire or a survey, and of course you are free to refuse to answer any questions or to stop the interview at any point. But, really, feel free to raise any issues that you think are important or central to some of the things that we discuss today. We really designed the questions to try to address some of the areas we think are key to understanding how you used REIKI with your child.

Also, I'm going to be using the word "child" even though _____ is an adolescent. Is that okay with you?

Before we get started, do you have any questions or concerns?

1. Tell me a little about your child.
    a. What kinds of symptoms are most distressing for your child?
    b. Can you describe how you manage those symptoms? Before REIKI? Please describe a typical day before the REIKI training.
2. Tell me about the REIKI training.
    a. How long did it take to learn?
    b. How difficult was it for you to learn? What about the practice – was it enough to make you feel comfortable with your ability to administer REIKI to your child?
    c. Was there anything about the training that you think should be changed for other parents?
3. So, you have had about 4 weeks to use REIKI with your child to help managing their symptoms.
    a. Can you describe how you typically use it?
    b. How often do you use it?
    c. How do you make the decision to use it?
    d. Would there be a situation that you might not use REIKI?
    e. Were there any particular symptoms that you felt were easier to manage using REIKI?
    f. Were there any symptoms that it just didn't work for?
    g. Can you describe a situation where using REIKI was particularly effective?

Pain and Anxiety Medication Log **Subject ID _____**

Date & Time	Medication	Dose	Reason	Comment
/ / _____am/pm				
/ / _____am/pm				
/ / _____am/pm				
/ / _____am/pm				
/ / _____am/pm				
/ / _____am/pm				
/ / _____am/pm				
/ / _____am/pm				

Subject ID _____

Parent Intervention Log

Date	Start Time	Session Minutes	Any Session Interruptions?	Where did the session take place?	Comments/Reactions to Session