270DP12053

NIH Dementia Proposal

Note to ad in- often elders symptoms may not reach the cut off for diagnosis but are minor depressed (p442 psychiatric epidemiology)

Questions raised by summary statement to be addressed in detailed three page response

Structure of response

1. The three- page response should be in outline format.
2. Quote or Paraphrase the criticism;
3. state if there was agreement, or if one or two reviewers thought this or that and then respond

1. **Remember to put the changes in the appropriate section of the plan and in this case might flag the change in the intro by saying that we have elaborated on this on page #?**
2. **And bracket the change in the text do not bold**

Respond to Human Subjects critic

1. How were the drop-out rates of 20% ascertained (1)

We based this on drop out rates of on-going in-home caregiver intervention research performed by Logdson et al (personal communication) which found drop-out rates for a longer study Pre-post assessment =12 wks) was 10% and at 6 months was 20%. Drop out was due to illness in either the caregiver or care receiver. We supposed that our study while of shorter duration (8 wks) also involved intervention receipt outside the home and believe that 20% is a reasonable expectation given the vagaries of life inherent in the study population

2 Is respite care the most appropriate controlled condition? (1,2)

We agree with reviewer #3 that "...respite is a practical intervention because it will likely answer and important question and.comparison to PT is unique because it may also be effective" We chose to compare an intervention that is ***a.*** *a standard of care and oft studied for caregiver stress and health effects,* ***b.*** *where efficacy has ranged from moderately effective in some cases to no effect on caregiver well-being at all,* ***c.*** *that provides something of value to the controls which would support adherence.* ***D.*** *to learn if PT has a significantly different impact than respite care. We believe the PT effect will*

be robust enough. It is important ***for future research design*** *in health services delivery and analysis of efficacy and economics of care.*
Why not use massage as a control? (1)

A1. How will we handle the data on the drop-outs. Statistically speaking

Is the current design large enough to allow for stratification of native/non native? (1, (2)

Reviewer 2 suggests that:

1. The attention placebo may have a sufficiently powerful effect to diminish the capacity to determine the efficacy of PT
2. That we do not say what will be done during respite care that there are no precise measures

—so what one reviewer sees as a weakness another sees as a strength

1. **there is no discussion about how respite will be financed or delivered**

Response

Our **future research** goals is to apply results to health services research since this is a major public health problem we want to know whether PT represents a cost-benefit intervention in comparison with other models.

In addition we may receive suggestive evidence of a mechanism of action, which we suspect is multi-leveled not often studied in caregiver intervention and this would inform the direction of our future research. We assigned a three-hour period to each group to address whether efficacy in PT could be attributed to just "time off" from care- giving.

We are not as concerned with defining what controls do during respite care. However we do agree it is a good idea to obtain data each week on each controls activities to analyze.

What will respite consist of? People will be free to leave their home to undertake any activity they chose or they may stay in the home while someone cares for the care recipient but if they remain in the home they will be instructed not to engage in conversation with the respite worker

How will respite be finannced?

The delivery of respite care is built into the budget. To support adherence we will deliver respite care through a. respite programs that currently supporting tribal peoples b. a local staffing agency c. volunteer respite staff eager to support this project.

This clinical study needs to show that study attention plus treatment is better that study attention only. We chose respite precisely because respite is not anything like PT yet there is standard approach to attention

C Reviewer # 2 suggest its not justified scientifically to include AI as it upsets the design

Why Indian? and issue of Indian stratification.

The Native/ non native is an important predictor. The stratification is for control, not for a separate analysis or comparison of native and non-native. The other reason to stratify is to determine whether the intervention and the assessment procedure/measures are feasible and acceptable to both native and non-native subjects. We should point out that we have identified our subjects as members of the Salish Indian group

We have carefully considered that we have a small sample size in this pilot study but know that the statistics will be robust enough to offset the sample size. There are several advantages, reviewers point out to inclusion of Native Americans, in particular a homogenous group from the Salish tribes in this study There is no a priori reason to assume that these two groups will respond differently, however we suggest that because the intervention is culturally congruent with the traditions of this reason that there is no inherent cultural obstacle.

While the results may not be conclusive they will be suggestive of trends that will inform our **larger study design**. Furthermore we believe that native and non-native will respond equally positively though possibly for different reasons. This data, obtained in the qualitative data would also inform **future research** .

Finally, we also chose Indian (Salish) populations because it is our organizational mandate that is reinforced by the NIH- NCCAM Strategic plan to address racial and ethnic disparities. AI populations are generally underserved and understudied for many reasons including population size (some tribes have 450 members) and the challenges inherent in operations; access, recruitment and adherence; feasibility and cultural congruency of protocols and interventions While the Salish population of western Washington small in the aggregate, it has a substantial presence with a growing need for services. An **Ro1** would have a sample size that could be stratified across ethnic differences larger study where there is a large enough sample for stratification across ethnic lines .

D. Reviewer 1: The data management plan is weak.

Refer to the data safety and monitoring plan. Add something that tightens up the tracking of data in the office and before its sent out.

E. Reviewer #2 The stress markers are well described but not synthesized. If it is just HPA axis- mediated stress reduction then respite will also have a pro-health benefit

What is the relationship between the stress markers?
Research in chronically stress people suggest that cori
We expect that the effects of PT will be robust enough to lead to a subjective sense of reduced stress and improved sense of well being measuring biological and physiological response to a bioenergy touch therapy, especially in this older, chronically stressed population is unknown. Relationship between cortisol We believe that the effects of PT extend beyond HPA mediated response perhaps due to interpersonal meaning and to the yet-to be-definedtheorized effects of biofield energy transfer and the phenomenological response often associated with, loss of attachment object transcendent states, religious or spiritual response. This is beyond the current scope of our research—but results here will help more narrowly define future mechanism of action
Nonetheless establishing a baseline of response is our goal if for example there is no change in the bio-physio measures but there is significant change in subjective reports, how does this inform our future measures in the larger study? It may significantly shift our definitions of what we are measures and lead to explore mechanism of action (see question #)

We chose the objective stress markers as simple non- invasive measures of biological and physiological change because

1. in similar touch-bioenergy modalities such as massage and Reiki, healing touch there is evidence that these markers reflect change and yet these markers have not been captured over a study of this duration;
2. PT has not been measured at all and one of the overall questions in touch-biofield interventions is exactly what kinds of measures will pick up change and at what point in the intervention and with what sample, e.g age etc..
3. We expect that people will say that they feel better on subjective/qualitative tests of stress and well being but in what way does it correlate with changes in the objective stress measures and which ones? This will also inform our future choice of measures.
4. It is also unknown if this population, older and stressed, will respond in this time period to the objective Stress markers such as cortisol and DHEA. Indeed very few if any caregiver or biofield therapy studies we found used cortisol over time (they used a one time pre and post treatment measure as a measure respond may or may not be responsive in this population
5. There is no data on these measures in the caregiver population or in the Salish Indian population and we feel it is essential gather baseline data on these markers of biological and physiological stress to understand their utility. Of note here is the research that suggests that acute stress leads to higher levels of salivary cortisol in chronic stress it is often lower so that this marker in particular may help define

change more than predefined idea of that change. It will be important to compare the relationship between change in HRV with change in the biological markers. We do not know which baseline our sample will fall in.

HR variability reduces naturally with age and it is unclear how HRV will respond to PT in this population. We feel though that as a measure of autonomic function linked to HPA axis function ....HRV analysis will measure immediate response as well as a long-term response

F. Data safety and Monitoring Plan

The data safety and monitoring needs a designated person The P.I. and the statistician someone else and a system of reporting This can be placed in the human subjects section along with a statement of human subjects protection training for all key personnel (we may want to address the low risk of this Rx. (MY suggestion) backed up with data—define the micro pressure of the form of touch or draw on reieki massage data or insurance industry data

Need to address:

3. Performance monitoring: to assess performance in respect to recruitment retention and follow-up, flow of data forms, protocol adherence and quality of data—this is done by the PI and statistician and reviewed by the safety officer.
4. Safety—assess magnitude of adverse events
5. Treatment-to monitor and assess treatment effects

Develop stopping rules>

How do we handle the drop-out data

G summary statement "possible co-morbidity of subjects"

Reviewer #2 Caregivers are often themselves elderly or ill and this may impact the differential response to respite vs. PT—This is not addressed This would have impact on subject # and analysis. Need to address information on morbidity

This is an important point. We have included symmetric exclusion criteria for controls and subjects. See P. We will also use a checklist of medical conditions and a medication list (caregivers list meds and doses) at pre-post-and follow up assessments. The physician will also ask caregivers if there's been any change in their health since the last assessment, and document it on a Health Change Data Form we have adapted to our subject pool from other dementia caregiver research.

Question for Nayak : How do we handle this data

H. Environment and resources section:

Reviewer 1 and 3 felt the environment and resources were adequate and appropriate.
Reviewer 2 asked:

1 It is not clear what the CWIS is: The CWIS is an independent non- profit research and educational organization that was chartered in 1984 in response to request by tribal governments in the pacific Northwest and Canada for a research and records center serving the needs of tribal peoples. It serves as a "think tank" of tribal and non- tribal investigators for research education and policy development in medicine, (Dr. Korn's agency) law and economics

2.What support it can provide Dr. Korn from an investigative perspective CWIS conducts professional development training and education collaborating with universities domestically and internationally; for university faculty, provides internships, fellowships and consultations for international visitors and states governments and collaborates with private and public sector partners in scientific meetings. Its staff including the key personnel on this project maintain strong relationships, including faculty appointments with universities and rich contacts and conduct research in a number of disciplines that enrich opportunities for innovation.

3 Access to a rich array of scientists may or may not exist and

4 it is not clear how the consultants will interact in a mutually fruitful way.

The development of this proposal was a collaborative effort among the team members and consultants. Consultants and key personnel have a close working relationship that supports effective and rapid communication based on intense interest in this study. Group email echanges and phone calls have proved effective and dynamic methods to bring people toegtehr who share common interests and various expertise across the gulf of some distance. However the Drs. Korn, Logsdon and Pollisar have met consistently as they are only an hour apart by car. The center is locted in the state capital and collegial with state and tribal agencies. Periodic conference calls and online simulcast exchange allow for exchange of ideas among the group.

I ***Note: This should be placed in the section on APPROACH.***

Reviewer 3: How in particular will the planned activities in this pilot study guide future research is not detailed in this application.

Reviewer 1 Results from a larger trial might have significant public health benefit particularly in certain populations such as native American

J. Summary: How in particular this research will serve to ground a substantive RO1 later.

Reviewer 3 -How in particular the planned activities will guide future research

Reviewer 2- says the study has the potential to lead to a larger study and to move CAM research forward.

Response1.provide the basis to determine safety and feasibility of delivery in native and non- native CAM friendly communities; determine the appropriateness of the choice of measures especially in relationship to qualitative information that emerges from treatment. Illuminate if there is a minimum Rx for effect-- the measures; refinement of the recruitment strategies; qualitative information may reveal factors that were not measured but that might point in the direction of new or additional measures; baseline of

changes that provide for next steps to examine synergistic effects of Rx for patients and caregivers (Reference in Schulz), effects of practitioner characteristics. Basis for building in long-term follow-up to see the duration of efficacy that will inform future protocol Interventions for caregivers are by nature multifaceted and PT may suggest affect behavioral physical emotional mental or spiritual functioning. One concept of PT is that it facilitates balance-- functional homeostasis in the individual (and practitioner) That people may achieve this respond positively may occur in a variety or ways for different reasons. This pilot study points us in the direction of these trends for a future study enabling us to add in measures or discard some.

K From Notes NIH review notes Statistician needs at least 15% assignment put this change in the resource section and attach a letter revised where he says that he will provide 15 % effort and accept 5 or 10% salary.

How and why will qualitative narratives be done (3)
On page 38 we review the qaulittaive approach we are taking.

The practitioners will undertake this assessment. Because the practitioners are blinded to all other aspects of the assessment this provides secondary information on evaluation and mental physical and emotional health status from a PT perspective
Polarity practitioners normally conduct a structured interview manual palpation and energetic assessment and evaluation guided by PT principles and theory. We have identified five assessments to include in the qualitative review that will be systematically charted. This affords the opportunity to evaluate efficacy in-its-own-terms and to compare practitioner observed change in relation to the objective and subjective measures This will further our understanding of future assessment methods for the delivery and allow for inter-method comparison.
These evaluation methods, drawn from the PT Standards for Practice include:
1. Check leg length as an indicator for contracted electromagnetic side as well as for prognosis indicator; 2. Check vital reserve capacity3. Observe expressions of face and head and eyes; 4 Note energy response to reestablishment of free rhythmic energy flow. (Reference P 14 standards for practice)
Each of these data is routinely collected along with qualitative information at each session. Following each session this data will be collected and stored by the data manager away from the other data and outside the access to the practitioners. At completion of the study the data will be compiled into a qualitative report and the specific assessment indicators quantified for comparison with other data by the statistician.

In this pilot study we aim to capture a wide range and type of information that support further refinement in the next phase of research. The system of Polarity therapy provides a standard for history- taking, evaluation and outcome assessment that is symptom-based and phenomenological based in the system of Polarity therapy. The value of undertaking narratives and analyzing them are three-fold.

1. to evaluate the experience of receiving polarity therapy from its own assessment methods.
2. Patient narratives and self reports that are obtained pre and post treatment contain the words comments and self assessment of the patient

There is no mention of other factors that influence HRV such as caffeine, exercise etc (3)

Should we add in a secondary outcome re the feasibility of the design and delivery of the intervention and control to native vs. non native can we say we are looking for a trend emphasize a future design

Re respite: my statement the reason e chose this is because its usual care and even though it it self may show some response.. Trying to ascertain if PT has significantly different impact that respite care but also within the qualitative data define if it has a qualitatively different impact that respite care(does this raise more statistics?
OK what are we doing re the qualitative analysis?

Go into detail on the nature of respite and how it will be provide. State w/o going into budget detail that its provision is included in the budget.

Review the data management plan

The data safety and monitoring needs a designated person (me and perhaps someone else and a system of reporting This can be placed in the human subjects section along with a statement of human subjects protection training for all key personnel (we may want to address the low risk of this Rx. (MY suggestion) backed up with data—define the micro pressure of the form of touch or draw on reieki massage data or insurance industry data

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Questions raised by summary statement to be addressed in detailed three page response

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Questions raised under section APPROACH:

estimate (Wayne)

A. How was the drop-our rate of 20% decided?

--Logsdon said she would find out her drop out rates .

A1. How will we handle the data on the drop-outs. Statistically speaking

B Reviewers 1 and 2 ask:

1.Is respite care the most appropriate controlled condition?

Review 1 asks

2. Why not use massage as a control?

Reviewer 2 suggests that:

1. The attention placebo may have a sufficiently powerful effect to diminish the capacity to determine the efficacy of PT
2. That we do not say what will be done during respite care that there are no precise measures

Reviewer 3 says

1. **Respite is a practical intervention it is likely to answer an important question and comparison to PT is unique because it may also be effective**
   --so what one reviewer sees as a weakness another sees as a strength
2. **there is no discussion about how respite will be financed or delivered**

Response

Why did we choose respite care? We evaluated many control possibilities: ranging from delivery of psycho educational materials other massage techniques. W chose to compare an intervention that is a. commonly used and studied for caregiver stress and health effects, b. that has shown diverse results when delivered in similar protocol ranging from moderately effective in some cases to no effect on caregiver well-being at all, c. that provides something of value to the controls which would support adherence to the program. We agree with reviewer 3 that it is a unique design and because we want to know if PT has a significantly different impact than respite care.

One of our future research goals is to apply information garnered here to health services research since this is a major public health problem we want to know whether PT represents a cost-benefit intervention in comparison with other models. In addition we may receive suggestive evidence of a mechanism of action, which we suspect is multi-leveled not often studied in caregiver intervention and this would inform the direction of our future research. We assigned a three-hour period to each group to address whether efficacy in PT could be attributed to just "time off" from care- giving. We are not as concerned with defining what controls do during respite care-indeed the capacity to self define that time reinforces the positives facets of respite provision and itself may reveal information for future study. However we do agree it is a good idea to obtain data on each controls activities each week as a record to analyze. The delivery of respite care is built into the budget. To support compliance we will deliver respite care through the respite programs supporting tribal peoples and through a local staffing agency and some volunteers eager to support this project.

Budget Question

Nayaka reponse YOU DO NEED TO COMPARE TREATMENT TO SOMETHING, AND THAT SOMETHING SHOULD
NOT BE TRIVIAL. I DON'T THINK THAT YOU SHOULD COMPARE TO NO TREATMENT OR
NO ATTENTION WHATSOEVER, BECAUSE THAT KIND OF "STANDARD TREATMENT" IS NOT
LIKELY TO HAPPEN. ALSO, YOU NEED TO GUARD AGAINST THE HAWTHORNE EFFECT,
WHEREBY PEOPLE WHO ARE STUDIED GET BETTER, JUST BECAUSE OF THE ATTENTION OR
WHATEVER MYSTERIOUS THINGS HAPPEN WHEN STUDIES FOCUS ON PEOPLE. I THINK
THAT THE BEST THING IS TO LOOK IN AN EPI OR CLINICAL STUDIES TEXT AND GET
SOME GOOD AMMUNITION AGAINST THIS. I AM WORKING ON ANOTHER STUDY WHERE WE
ARE FACING THE SAME ISSUE, AND WE ARE TRYING TO GIVE THE CONTROL GROUP AS
MUCH ATTENTION AS THE TREATMENT GROUP, BUT THE CONTENT OF THE ATTENTION IS
DIFFERENT.

IN ANY CASE, THE BOTTOM LINE IS THAT THIS CLINICAL TRIAL NEEDS TO SHOW THAT
STUDY ATTENTION PLUS TREATMENT IS BETTER THAN STUDY ATTENTION ONLY. THE
RESPITE CARE SEEMS GOOD TO ME, BECAUSE NO ONE CAN ARGUE THAT IT IS ANYTHING
LIKE THE POLARITY THERAPY, YET THERE IS SOMETHING BEING DONE FOR THE PEOPLE--SOME ATTENTION.

Touch Sentability unknown

C Reviewer # 2 Maybe the native American caregivers are the best group with which to begin this work, although this is an assumption. The says its not justified cientifcally to include AI as it upsets the design
Why Indian? and issue of Indian stratification.
We have carefully considered that we have a small sample size in this pilot study but know that the statistics will be robust enough to offset the sample size. There are several advantages, reviewers point out to inclusion of Native Americans, in particular a homogenous group from the salish tribes in this study There is no a priori reason to assume that these two groups will respond differently however I satted that because the intervention is culturally congruent with the traditions of this reason that there is no obstacle. To use and indeed may suggest it is even more effective due to cultural influences However the use of biofield touch therapies is widely used in the non native communities here as well by people of all ages and socio- economic status.
While the results may not be conclusive they will be suggestive of trends that will inform our larger study design. Furthermore we believe that native and non-native will respond equally positively though possibly for different reasons. These factors may be suggested in qualitative data. This would also refine future research .
We also chose Indian (salish) populations because it is our organizational mandate that is reinforced by the NCCAm strategic plan to address racial and ethnic disparities. AI populations are generally underserved and understudied for many reasons including population size (some tribes have 450 members) and the challenges inherent in operations; access, recruitment and adherence; feasibility and cultural congruency of protocols and interventions This study includes Salish population members. There are many reasons why Natives are underserved and understudied. Access and protocol feasibility is one. In the Salish population of western Washington the eligible sample size is small, but growing-- methods for recruitment and enrollment are different for native vs. non native. Because this is a feasibility study we will obtain secondary outcome data on the feasibility of the study protocol with native and non native in order to analyze have data for a larger study where there is a large enough sample for stratification across ethnic lines .
The stratification is for control, not for a separate analysis or comparison of native and non-native. The other reason to stratify is to determine whether the intervention and the assessment procedure/measures are feasible and acceptable to both native and non-native subjects. (RL)
THE NATIVE/NON-NATIVE IS AN IMPORTANT PREDICTOR, AND THAT

WE SHOULD STRATIFY ON THIS PRIOR TO RANDOMIZATION (AS A METHOD OF CONTROL, AND NOT IN ORDER TO ANALYZE EACH SEPARATELY) (**NP**)

Data Safety & Monitoring

D. Reviewer 1: The data management plan is weak.
---Review the areas for collection and delivery (pp 32-33) and see where we can improve

E. Reviewer #2 The stress markers are well described but not synthesized. If it is just HPA axis- mediated stress reduction then respite will also have a pro-health benefit

We expect that the effects of PT will be robust enough to lead to a subjective sense of reduced stress and improved sense of well being. However measuring biological and physiological response to a bioenergy touch therapy, especially in this older, chronically stressed population is murkier. We believe that the effects of PT are more complex than HPA mediated response perhaps due to interpersonal meaning and to the yet-to be-definedtheorized effects of biofield energy transfer and the phenomenological response often associated with, loss of attachment object transcendent states, religious or spiritual response. This is beyond the current scope of our research—but results here will help more narrowly define future mechanism of action

Nonetheless establishing a baseline of response is our goal if for example there is no change in the bio-physio measures but there is significant change in subjective reports, how does this inform our future measures in the larger study? It may significantly shift our definitions of what we are measures and lead to explore mechanism of action (see question #)

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3. We expect that people will say that they feel better on subjective/qualitative tests of stress and well being but in what way does it correlate with changes in the objective stress measures and which ones? This will also inform our future choice of measures.
4. It is also unknown if this population, older and stressed, will respond in this time period to the objective Stress markers such as cortisol and DHEA. Indeed very few if any caregiver or biofield therapy studies we found used cortisol over time (they used a one time pre and post treatment measure as a measure respond may or may not be responsive in this population
5. There is no data on these measures in the caregiver population or in the Salish Indian population and we feel it is essential gather baseline data on these markers of biological and physiological stress to understand their utility. Of note here is the research that suggests that acute stress leads to higher levels of salivary cortisol in

chronic stress it is often lower so that this marker in particular may help define change more than predefined idea of that change. It will be important to compare the relationship between change in HRV with change in the biological markers. We do not know which baseline our sample will fall in.

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5. Treatment-to monitor and assess treatment effects

Develop stopping rules>

G summary statement "possible co-morbidity of subjects"
Reviewer #2 Caregivers are often themselves elderly or ill and this may impact the differential response to respite vs. PT—This is no t addressed This would have any impact on subject # and analysis. Need to address information on morbidity

Do we need another scale of health function? Or to more strictly define health criteria. We need somehow to more strictly define enrollment criteria vis a vis this question. We do have a section in the criteria that says no major disability. But the fact is we are assuming people are not well. I suppose we could include a records review OR make use of the MD-examiner in some way.

Place in environment or after

H. Environment and resources section:

Reviewer 1 and 3 felt the environment and resources were adequate and appropriate ~~Reviewer 2 posed~~ the following questions, which I will respond to briefly here and elaborate further in the environment and resources section

1 It is not clear what the CWIS is: The CWIS is an independent non- profit research and educational organization that was developed in 1984 in response to request by tribal

governments in the pacific Northwest and Canada for a research and records center serving the needs of tribal peoples. It serves as a "think tank" of tribal and non- tribal investigators for research and policy development in medicine, (Dr. Korn's agency) law and economics. **and**
2.What support it can provide Dr. Korn from an investigative perspective It also conducts professional development training and education for university faculty, provides internships, fellowships and consultations for international visitors and states governments and collaborates with private and public sector partners in scientific meetings. Its staff including the key personnel on this project maintain strong relationships, including faculty appointments with universities and rich contacts and conduct research in a number of disciplines that enrich opportunities for innovation.

3 Access to a rich array of scientists may or may not exist and
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I ***Note: This should be placed in the section on APPROACH.***
Reviewer 3: How in particular will the planned activities in this pilot study guide future research is not detailed in this application.
Reviewer 1 : Results from a larger trial might have significant public health benefit particularly in certain populations such as native American

6-18-12

J. Summary: How in particular this research will serve to ground a substantive RO1 later.
Reviewer 3 -How in particular the planned activities will guide future research
Reviewer 2- says the study has the potential to lead to a larger study and to move CAM research forward.
Response1.provide the basis to determine safety and feasibility of delivery in native and non- native CAM friendly communities; determine the appropriateness of the choice of measures especially in relationship to qualitative information that emerges from treatment. Illuminate if there is a minimum Rx for effect-- the measures; refinement of the recruitment strategies; qualitative information may reveal factors that were not measured but that might point in the direction of new or additional measures; baseline of changes that provide for next steps to examine synergistic effects of Rx for patients and caregivers (Reference in Schulz), effects of practitioner characteristics. Basis for building in long-term follow-up to see the duration of efficacy that will inform future protocol

Interventions for caregivers are by nature multifaceted and PT may suggest affect behavioral physical emotional mental or spiritual functioning. One concept of PT is that it facilitates balance-- functional homeostasis in the individual (and practitioner) That people may achieve this respond positively may occur in a variety or ways for different reasons. This pilot study points us in the direction of these trends for a future study enabling us to add in measures or discard some.

K From Notes NIH review notes Statistician needs at least 15% assignment put this change in the resource section and attach a letter revised where he says that he will provide 15 % effort and accept 5 or 10% salary.

RCR

L. reviewer 3 # How and why will qualitative narratives be done.
On page 38 this is reviewed .is the problem placement and should we move to the tests? Do we need to revise?
The practitioners will undertake this assessment. Because the practitioners are blind to all other aspects of the assessment this will provide secondary information on evaluation and mental physical and emotional health status from a PT perspective

New item: We will incorporate amore detailed Polarity therapy assessment. The practitioners normally conduct a structured assessment and evaluation guided by PT principles and theory. We have chosen five assessments to include in the qualitative review that will then be charted and systematized. This afford s the opportunity to evaluate efficacy in the method -its-own-terms and to compare. This will further our understanding of future assessment methods for the delivery and allow for inter-method comparison.

These evaluation methods, drawn from the PT Standards for Practice include:
1. Check leg length as an indicator for contracted electromagnetic side as well as for prognosis indicator; 2. Check vital reserve capacity3. Observe expressions of face and head and eyes; 4 Note energy response to reestablishment of free rhythmic energy flow. (Reference P 14 standards for practice)
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combined and plug in @ page 38

In this pilot study we aim to capture a wide range and type of information that support further refinement in the next phase of research. The system of Polarity therapy provides a standard for history- taking, evaluation and outcome assessment that is symptom-based and phenomenological based in the system of Polarity therapy. The value of undertaking narratives and analyzing them are three-fold.
1. to evaluate the experience of receiving polarity therapy from its own assessment methods.

2. Patient narratives and self reports that are obtained pre and post treatment contain the words comments and self assessment of the patient

Should we add in a secondary outcome re the feasibility of the design and delivery of the intervention and control to native vs. non native can we say we are looking for a trend emphasize a future design

Under the resources section in the grant make your statement about who the CWIS is and the rich nature of exchange with the collaborators

Address qualitative issue

Re respite: my statement the reason e chose this is because its usual care and even though it it self may show some response.. We believe the PT effect will be robust enough. It is important for future research design in health services delivery and analysis of efficacy and economics of care. Trying to ascertain if PT has significantly different impact that respite care but also within the qualitative data define if it has a qualitatively different impact that respite care(does this raise more statistics?
OK what are we doing re the qualitative analysis?

Go into detail on the nature of respite and how it will be provide. State w/o going into budget detail that its provision is included in the budget.

Review the data management plan

The data safety and monitoring needs a designated person (me and perhaps someone else and a system of reporting This can be placed in the human subjects section along with a statement of human subjects protection training for all key personnel (we may want to address the low risk of this Rx. (MY suggestion) backed up with data—define the micro pressure of the form of touch or draw on reieki massage data or insurance industry data

M. What will do with drapaut data?