Just... Breathe: Virtual Reality Guided Breathing Exercise for Anxiety Management in Amyotrophic Lateral Sclerosis

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PROTOCOL SUMMARY

Virtual Reality (VR) is gaining traction as a new and innovative leisure to augment healthcare services. Several benefits of the leisure experience, such as distraction and full sensory immersion, have demonstrated a potential to significantly impact the field of healthcare through pain reduction, anxiety reduction, and is seen as an innovative approach to motor learning. Persons with ALS (pwALS) have a high prevalence of anxiety over the course of their illness, which has a negative impact on their quality of life, and the quality of life of those closest to them. The use of VR for anxiety management and subsequent quality of life improvement has yet to be explored in the ALS population.

For individuals with ALS, VR can be both (1) an escape from the reality of living day to day with a progressive fatal diagnosis; and (2) the opportunity to potentially improve anxiety, both of which are linked to the quality of life of individuals living with ALS. Our hypothesis is that a simple and accessible home VR-guided relaxation exercise program can improve subjective anxiety symptoms in a person living with ALS and subsequently improve quality of life.

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Background

Amyotrophic lateral sclerosis (ALS) is a neuromuscular disease characterized by death of motor neurons, resulting in weakness[1]. Aside from motor-related progressive impairment, persons with ALS (pwALS) experience a burden of non-motor symptoms which have major influences on quality of life (QOL)[2]. This includes anxiety, found to be only second to function as greatest influence on QOL[3], and autonomic dysfunctions such as dyspnea, heart rate variability, and dizziness. Such autonomic dysfunctions are also symptoms often experienced with anxiety[4]. The prevalence of anxiety in persons with ALS ranges from 20.5-67.6%, is shown to fluctuate over the course of the illness, and is recognized to have a negative effect on the quality of life of not only those affected, but also their caregivers[2,5]. A study by Marconi and colleagues[6] identified that late-stage ALS patients exhibited high levels of anxiety, while a study by Vignola et al.[7] found higher anxiety levels during the diagnostic and early stages of the disease. Despite its high prevalence and presence over the course of illness, anxiety is not always a properly addressed aspect of ALS, with limited literature regarding interventions[8]. As anxiety has been shown to have a causal relationship that can lead to decreased quality of life[3,9], further research is essential to find methods to reduce anxiety and subsequently improve QOL for persons with ALS.

Quality of life (QOL) is defined by the World Health Organization as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" ("WHO | WHOQOL"). Included in this definition is the person's physical health, psychological state, personal beliefs, social relationships, and relationships with salient features of the environment. High levels of physical disability are linked to a lower predictor of quality of life, and with a neuromuscular disease such as ALS, an individual's ability to engage with their community and environment deteriorates, resulting in fewer opportunities to engage in leisure and recreation that have a direct implication on one's quality of life[11,12]. Any recreation opportunity that offers an element of enjoyment and freedom should be explored[12].

Exploring alternative technologies to improve access to anxiety management strategies for pwALS is a worthy endeavor. Virtual Reality (VR) is a technology increasingly used for mental health treatment and within clinical research[13]. The virtual reality aspect allows for the person to be fully immersed in a relaxing environment with visual and auditory stimuli which has relaxation effects similar to meditation[14]. Anxiety treatment interventions utilizing VR can include exposure therapy or applied relaxation techniques, two of the more promising treatments for generalized anxiety disorder, often promoting similar results to such traditional techniques[15-18]. VR facilitates the applied relaxation intervention by visually presenting key relaxing images to the subjects[19]. The visual presentation of a virtual calm scenario can facilitate a persons' practice and mastery of relaxation, making the experience more vivid and real than the one that most individuals can create using their own imagination and memory[19].

Despite the increasing use of VR in the treatment of various mental health diagnoses, the use of VR in pwALS is innovative[20]. Currently, there is very limited research available exploring the effects of using VR relaxation

techniques on anxiety or QOL in pwALS. As VR is increasingly shown to provide benefits for the user, additional research is required to identify benefit to this population.

The Present Study

This study will identify if a simple and accessible home VR guided relaxation exercise program can improve subjective anxiety symptoms in persons living with ALS, subsequently improving quality of life.

Hypothesis

Engaging in a simple and accessible home-based virtual reality (VR) guided relaxation exercise program will show a reduction in subjective anxiety symptoms and subsequent improvement in quality of life in persons with ALS.

METHODS

Participants

At 5 sites across Canada (Fredericton NB, Halifax NS, Kingston ON, Hamilton ON, and Saskatoon SK), persons with Amyotrophic Lateral Sclerosis will be identified by their treating physician and invited to participate during a typical interdisciplinary ALS clinic visit at their respective healthcare centre.

Sample Size and Power Analysis
Literature with similar interventions with ALS patients shows effect sizes ranging from zero (no effect) to medium (f = .25), so a median effect size of f = .175 gives good balance between null and medium effect[21]. With an alpha of .05 and 80% power, power analysis with the median effect size of f = .175 and 4 outcome assessments while accounting for a 20-30% attrition rate puts the required sample size at 60 participants across the 5 participating sites. Participants will be randomized through block randomization methods into either control or intervention groups (6 control and 6 intervention participants per site).

Inclusion criteria:

- Diagnosed with ALS (gold coast or El-Escorial), or ALS variants of flail limb, progressive muscle atrophy, UMN or LMN predominant
- Able to use VR device with no negative effects (i.e. headaches, vision changes, dizziness, nausea, disorientation)

Exclusion criteria:

- Cognitive impairment that impacts ability to participate fully in assessments

Timeframe

Pending REB approvals, data sharing agreements, and equipment procurement, we anticipate starting recruitment in Fall 2025. We anticipate this project to be completed within 24 months. Subjects 1-30 are planned to be recruited and complete the study within an 8–9-month timeframe, as well as subjects 31-60, with some overlap. Considering time for recruitment struggles or dropouts, data analysis, and dissemination, this will bring us to 21-24 months for total project completion.

Measures/Materials

Participants will be provided with a VR Oculus Meta Quest 3 device with the 'Tripp' guided breathing application installed, a paired tablet for casting their screen to allow caregivers to aid the user if needed, and a VR usage log. Assessments used will include the State Trait Inventory for Cognitive and Somatic Anxiety (STICSA), ALS Functional Rating Scale – Revised (ALSFRS-R), ALS-Specific Quality of Life Short Form (ALSSQOL-SF), and Patient Global Impression of Improvement Scale (PGI-I). These will be used to assess participant anxiety, global functions, quality of life, and whether they are perceiving any changes in such areas, respectively.

The STICSA is a self-report questionnaire consisting of 42-items rated on a 4-point Likert scale from 1 *(Almost never or Not at all)* to 4 *(Almost always or Very much so)*, where 21 items are rating how you feel in the present moment, and the same 21 items are rated based on how you feel in general[22]. The validity of the STICSA has been examined in many different cases[23,24], as well examined with different age groups[25,26]. A study done with an elderly sample stated "The STICSA also showed evidence of discriminating anxious symptoms from physical

health symptoms"[25]. The STICSA has also been compared against the well-known State-Trait Anxiety Inventory anxiety measure, finding that STICSA has better convergent validity with measures of somatic anxiety[23].

The ALS Functional Rating Scale (ALSFRS) is a validated rating instrument for monitoring the progression of disability in persons with ALS[27]. The Revised ALSFRS (ALSFRS-R) retains the properties of the original scale and shows strong internal consistency and construct validity[27]. The scale consists of 12 items, each with 5 possible responses rating impairment level, and covers various aspects of daily living[27]. ALSFRS-R scores correlate significantly with quality of life as measured by the Sickness Impact Profile, indicating that the quality of function is a strong determinant of quality of life in ALS[27]. It is a primary outcome measure used in clinical trials of ALS because it is validated, easy to administer, minimizes dropout, reduces cost, and correlates with survival[28].

The Amyotrophic Lateral Sclerosis-Specific Quality of Life instrument and its revised version (ALSSQOL and ALSSQOL-R) have strong psychometric properties and have demonstrated research utility[29]. To reduce assessment time, we will utilize the short-form version in this study (ALSSQOL-SF). Compared with the ALSSQOL-R, optimal precision was retained, and psychometric properties for the ALSSQOL-SF and its subscales were strong[29]. The ALSSQOL-SF is a 20-item disease-specific global QOL instrument that has a short administration time suitable for clinical use, and can provide clinically useful, valid information about persons with ALS[29]. Items are scored using a 0-10 rating scale[29].

Patient global impression of improvement (PGI-I) is a single-item global rating of change scale that asks an individual to rate the severity of a specific condition at baseline or to rate at endpoints the perceived change in his/her condition in response to therapy[30]. There are seven possible responses (scored 1–7): very much better, much better, a little better, no change, a little worse, much worse, and very much worse[30]. The PGI-I can provide an overall patient-centric appraisal of their own condition[30]. We will be using it alongside the other measures mentioned above to assess change.

Copies of all assessments are included in the Appendix.

Procedure

Once participants are referred from their physician to research team members, the study will proceed as follows:

1. At baseline visit, participants will meet with a member of the research team at their respective site for informed consent discussion and collection of general demographic information such as sex, age, time since ALS diagnosis, and other diagnoses as some may affect results (i.e. diagnosed and/or treated mental health history). All participants will complete the STICSA, ALSFRS-R, and the ALSSQOL-SF to obtain baselines for state trait anxiety, current functional ability, and quality of life, respectively. If randomized to the intervention group, participants will complete training with the VR equipment through tutorial videos and research team guidance.

2. Participants in the intervention group will receive the VR headset and instructions to take home and be asked to use the app 3x/week while maintaining a VR usage log. Participants in the control group will be advised to carry on as normal.

3. At the end of Week 4, <u>all</u> participants will be contacted via telephone to repeat the STICSA and ALSSQOL-SF, and intervention group participants will have a technology check-in.

4. At the end of Week 8, <u>all</u> participants will be contacted again via telephone to repeat the STICSA and ALSSQOL-SF, and intervention group participants will have a technology check-in.

5. At the end of Week 12, participants will be seen in clinic or home for the end-of-study visit, where they will complete the STICSA, ALSFRS-R, ALSSQOL-SF, PGI-I, and general study wrap-up activities (i.e., equipment return). As a thank you for participating, those in the control group will have the opportunity to trial a VR guided breathing session if they wish. If in the control group and do not wish to trial VR, this step may be done over the phone.

6. At participants' next ALS clinic 3 months post-study or over the phone, a follow-up will be conducted to ensure participants have no major declines in function or mental status. Participants will complete the STICSA, ALSFRS-R, and ALSSQOL-SF.

Study Design

This study is a prospective randomized controlled trial (RCT).

Sampling Procedures

The primary site of this project is Stan Cassidy Centre for Rehabilitation, a tertiary neurorehabilitation centre in Fredericton, New Brunswick. However, participants will be recruited at additional healthcare sites in Nova Scotia, Ontario, and Saskatchewan. Eligible participants will be identified by their treating physician and invited to participate during a typical interdisciplinary ALS clinic visit at their respective healthcare centre. The physician will give a brief description of the project and ask permission for a research team member to contact them about participation and conduct informed consent discussions. Block randomization method will assign consenting participants at each site to either the intervention or control group.

There will be no financial compensation for participation as there are no costs or financial burdens on participants in this study. As a thank you to the participants in the control group, they will be allowed to trial the VR guided breathing sessions after completion of their follow-up visit.

Specification of the Variables under Investigation

The independent variable in this study is the introduction or absence of the VR-guided relaxation exercise program. The dependent variable is participant's subjective anxiety symptoms and consequently quality of life. Outcome variables will include the STICSA, ALSFRS-R, ALSSQOL-SF, and PGI-I.

Data Collection, Storage, and Retention

Data collection and assessments will be conducted by research team members, including research assistants and coordinators under the primary and co-applicants' supervision, who all have training certifications in place regarding confidentiality, privacy, and research ethics. Baseline collection will be completed in-person after ALS clinics. Assessments done at Weeks 4 and 8 will be completed over the phone. Final assessment and wrap-up will be completed in-person either at home or in clinic, or over the phone if part of the control group who do not wish to come in and trial the VR. Final follow-up visit will be conducted either in clinic or over the phone.

Sites may conduct assessments on paper or enter responses directly into RedCap, which is a secure, web-based software platform designed for building and managing online surveys and databases.. Each site will be provided with study access to RedCap for data entry, with analysis being completed at the lead site following completion of the study.

The primary study site is Stan Cassidy Centre for Rehabilitation in Fredericton, N.B. Any local paper study documentation will be kept in a double-locked cabinet within the SCCR Research Office accessible only to members of the research team at SCCR. Data at all sites will be de-identified and collected on encrypted computers with password protected data files and kept safely at their respective sites. Data sharing agreements will be drafted between the primary site and all other sites for safe transfer over email once collection is complete. Data analysis will be conducted by the primary site's research team. Once completed, the data will be transferred onto an encrypted USB drive or computer. Any documentation and USB drive will be archived for 7 years after the study's completion and then destroyed.

Proposed Data Analysis

Participant demographic information will be described using descriptive statistics. There will be consideration of demographic statistics when comparing outcome measures between groups (i.e. variations in sex, age, function) if the groups do not have similar profiles, though we are aiming for equivalent grouping.

Comparative analysis looking at the interaction effect between intervention and control groups over time using a mixed repeated-measures analysis of variance (mixed RM-ANOVA) will be performed to determine statistical differences in score outcomes of the STICSA, ALSSQOL-SF, and PGI-I. Critical alpha will be set to 0.05 for all statistical tests. As the STICSA includes subscales measuring cognitive and somatic components of both state and trait anxiety, these subscales (state and trait) will be analyzed using RM-ANOVA separately in a two-factor model, as it has found to yield more robust, precise scoring and interpretation[31]. The ALSFRS-R will be used to assess disease progression pre- to post-study to ensure no major declines occurred during the study period and to gauge general functional ability of the participant population. Data visualization will be undertaken of all quantitative variables using histograms and other basic descriptive statistics (e.g., mean, maximum, count) and scatterplot graphs.

Conclusion

This multi-site randomized controlled trial aims to identify if a simple and accessible at-home virtual reality guided relaxation exercise program can improve subjective anxiety symptoms in persons with ALS and subsequently improve quality of life. It is our hope that this project will not only raise mental health awareness in persons with ALS but also provide an accessible and affordable opportunity to manage these overlooked aspects of ALS. This work could potentially be applied to other diagnoses which influence mental health and quality of life if deemed effective.

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Appendices

- ***Appendix A:*** State Trait Inventory for Cognitive and Somatic Anxiety (STICSA)
- ***Appendix B****:* ALS Functional Rating Scale – Revised (ALSFRS-R)
- ***Appendix C:*** ALS-Specific Quality of Life Short Form (ALSSQOL-SF)
- ***Appendix D:*** Patient Global Impression of Improvement Scale (PGI-I)
- ***Appendix E****:* Study Budget
- ***Appendix F****:* Excel Data Collection Template (attached separately)

Appendix A – State Trait Inventory for Cognitive and Somatic Anxiety

STICSA- TRAIT

Below is a list of statements which can be used to describe how people feel. Beside each statement are four numbers which indicate **how often each statement is true of you** (eg, 1 = almost never, 4 = almost always). Please read each statement carefully and circle the number which best indicates **how often, in general, the statement is true of you.**

	Not at all	A little	Moderately	Very much so
1. My heart beats fast	1	2	3	4
2. My muscles are tense	1	2	3	4
3. I feel agonized over my problems	1	2	3	4
4. I think that others won't approve of me	1	2	3	4
5. I feel like I'm missing out on things because I can't make up my mind	1	2	3	4
6. I feel dizzy	1	2	3	4
7. My muscles feel tense	1	2	3	4
8. I feel trembly and shaky	1	2	3	4
9. I picture some future misfortune	1	2	3	4
10. I can’t get some thought out of my mind	1	2	3	4
11. I have trouble remembering things	1	2	3	4

12. My face feels hot	1	2	3	4
13. I think the worst will happen	1	2	3	4
14. My arms and legs feel stiff	1	2	3	4
15. My throat feels dry	1	2	3	4
16. I keep busy to avoid uncomfortable thoughts	1	2	3	4
17. I cannot concentrate without irrelevant thoughts intruding	1	2	3	4
18. I worry that I cannot control my thoughts as well as I would like to	1	2	3	4
19. I worry that I cannot control my thoughts as well as I would like to	1	2	3	4
20. I have butterflies in my stomach	1	2	3	4
21. My palms feel clammy	1	2	3	4
Column totals	=	=	=	=
Total Score =				

STICSA- STATE

Below is a list of statements which can be used to describe how people feel. Beside each statement are four numbers which indicate **the degree with which each statement is self-descriptive of mood at this moment** (e.g., 1 = not at all, 4 = very much so). Please read each statement carefully and circle the number which best indicates **how you feel right now, at this very moment, even if this is not how you usually feel.**

	Not at all	A little	Moderately	Very much so
1. My heart beats fast	1	2	3	4
2. My muscles are tense	1	2	3	4
3. I feel agonized over my problems	1	2	3	4
4. I think that others won't approve of me	1	2	3	4
5. I feel like I'm missing out on things because I can't make up my mind	1	2	3	4
6. I feel dizzy	1	2	3	4
7. My muscles feel tense	1	2	3	4
8. I feel trembly and shaky	1	2	3	4
9. I picture some future misfortune	1	2	3	4
10. I can’t get some thought out of my mind	1	2	3	4
11. I have trouble remembering things	1	2	3	4

12. My face feels hot	1	2	3	4
13. I think the worst will happen	1	2	3	4
14. My arms and legs feel stiff	1	2	3	4
15. My throat feels dry	1	2	3	4
16. I keep busy to avoid uncomfortable thoughts	1	2	3	4
17. I cannot concentrate without irrelevant thoughts intruding	1	2	3	4
18. I worry that I cannot control my thoughts as well as I would like to	1	2	3	4
19. I worry that I cannot control my thoughts as well as I would like to	1	2	3	4
20. I have butterflies in my stomach	1	2	3	4
21. My palms feel clammy	1	2	3	4
Column totals	=	=	=	=
Total Score =				

Appendix B - Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R)

Participant ID# _____
Date: _____

QUESTIONS

1. Speech
☐ 4 – Normal Speech processes
☐ 3 – Detectable speech with disturbances
☐ 2 – Intelligible with repeating
☐ 1 – Speech combined with nonvocal communication
☐ 0 – Loss of useful speech

2. Salivation
☐ 4 – Normal
☐ 3 – Slight but definite excess of saliva in mouth; may have nighttime drooling
☐ 2 – Moderately excessive saliva; may have minimal drooling
☐ 1 – Marked excess of saliva with some drooling
☐ 0 – Marked drooling; requires constant tissue or handkerchief

3. Swallowing
☐ 4 – Normal eating habits
☐ 3 – Early eating problems – occasional choking
☐ 2 – Dietary consistency changes
☐ 1 – Needs supplemental tube feeding
☐ 0 – NPO (exclusively parenteral or enteral feeding)

4. Handwriting
☐ 4 – Normal
☐ 3 – Slow or sloppy; all words are legible
☐ 2 – Not all words are legible
☐ 1 – Able to grip pen but unable to write
☐ 0 – Unable to grip pen

5. Does subject have gastrostomy?
☐ No – Answer 5a
☐ Yes – Answer 5b

a. Cutting Food and Handling Utensils (patients without gastrostomy)
☐ 4 – Normal
☐ 3 – Somewhat slow and clumsy, but no help needed
☐ 2 – Can cut most foods, although clumsy and slow; some help needed
☐ 1 – Food must be cut by someone, but can still feed slowly
☐ 0 – Needs to be fed

5. (cont.)

b. Cutting Food and Handling Utensils (alternate scale for patients with gastrostomy)

☐ 4 – Normal
☐ 3 – Clumsy but able to perform all manipulations independently
☐ 2 – Some help needed with closures and fasteners
☐ 1 – Provides minimal assistance to caregivers
☐ 0 – Unable to perform any aspect of task

6. Dressing and Hygiene

☐ 4 – Normal function
☐ 3 – Independent and complete self-care with effort or decreased efficiency
☐ 2 – Intermittent assistance or substitute methods
☐ 1 – Needs attendant for self-care
☐ 0 – Total dependence

7. Turning in bed and adjusting bed clothes

☐ 4 – Normal
☐ 3 – Somewhat slow and clumsy, but no help needed
☐ 2 – Can turn alone or adjust sheets, but with great difficulty
☐ 1 – Can initiate, but not turn or adjust sheets alone
☐ 0 – Helpless

8. Walking

☐ 4 – Normal
☐ 3 – Early ambulation difficulties
☐ 2 – Walks with assistance
☐ 1 – Nonambulatory functional movement only
☐ 0 – No purposeful leg movement

9. Climbing Stairs

☐ 4 – Normal
☐ 3 – Slow
☐ 2 – Mild unsteadiness or fatigue
☐ 1 – Needs assistance
☐ 0 – Cannot do

Appendix C - ALS-Specific Quality of Life Short Form (ALSSQOL-SF)

Participant ID# _____

Date: _____

Instructions:

The questions in this questionnaire begin with a statement followed by two opposite answers. Numbers extend from one extreme answer to its opposite. Please circle the number between 0 and 10 which is most true for you. There are no right or wrong answers. Completely honest answers will be most helpful.

Please assess your overall quality of life over the past week (7 days):

	Very bad										Excellent
Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past week, the quality of my life has been.	0	1	2	3	4	5	6	7	8	9	10

Please rate the following symptoms and experiences according to how much of a problem each one has been for you. Please respond about how you have felt or what you have experienced over the past week using the scale provided.

		No Problem										Tremendous Problem
1.	Pain	0	1	2	3	4	5	6	7	8	9	10
2.	Fatigue	0	1	2	3	4	5	6	7	8	9	10
3.	Excessive Saliva	0	1	2	3	4	5	6	7	8	9	10
4.	Speaking	0	1	2	3	4	5	6	7	8	9	10
5.	My Strength and Ability to Move	0	1	2	3	4	5	6	7	8	9	10
6.	Sleep	0	1	2	3	4	5	6	7	8	9	10

Please rate the following statements according to how strongly you agree or how strongly you disagree with each of them. Please respond about how you have felt or what you have experienced over the past week.

		Strongly Disagree										Strongly Agree
7.	I have felt physically terrible	0	1	2	3	4	5	6	7	8	9	10
8.	The world has been caring and responsive to my needs	0	1	2	3	4	5	6	7	8	9	10
9.	I have felt supported	0	1	2	3	4	5	6	7	8	9	10

Please rate the following statements according to how much you have felt or experienced what is described. Please respond about how you have felt or what you have experienced over the past week.

		Not at all										Very much
10.	I have been depressed	0	1	2	3	4	5	6	7	8	9	10

11.	Relationships have been satisfying	0	1	2	3	4	5	6	7	8	9	10
12.	My religion has been a source of strength/comfort to me	0	1	2	3	4	5	6	7	8	9	10
13.	I consider myself to have been religious or spiritual	0	1	2	3	4	5	6	7	8	9	10
14.	I have felt hopeless	0	1	2	3	4	5	6	7	8	9	10
15.	I have felt sad	0	1	2	3	4	5	6	7	8	9	10
16.	I have enjoyed the beauty of my surroundings	0	1	2	3	4	5	6	7	8	9	10

The following statements are about emotional intimacy (for example, sharing deep, private thoughts; feeling connected). Please think about your experiences with or how you have felt about emotional intimacy in the past week, and use the scales provided below to respond.

		Strongly Disagree										Strongly Agree
17.	My desire for emotional intimacy has been strong	0	1	2	3	4	5	6	7	8	9	10
18.	I have shared emotional intimacy with others	0	1	2	3	4	5	6	7	8	9	10

The following statements are about physical intimacy (for example, touching, hugging, kissing). Please think about your experiences with or how you have felt about physical intimacy in the past week, and use the scales provided below to respond.

		Strongly Disagree										Strongly Agree

19.	My desire for physical intimacy has been strong	0	1	2	3	4	5	6	7	8	9	10
20.	I have shared physical intimacy with others	0	1	2	3	4	5	6	7	8	9	10

Appendix D - Patient Global Impression of Improvement (PGI-I) Scale

Participant ID# _____

Date:

1. What best describes how your anxiety is now, compared to how it was before you started the VR guided breathing sessions?

    - Very much better
    - Much better
    - A little better
    - No change
    - A little worse
    - Much worse
    - Very much worse

2. What best describes how your quality of life is now, compared to how it was before you started the VR guided breathing sessions?

    - Very much better
    - Much better
    - A little better
    - No change
    - A little worse
    - Much worse
    - Very much worse

Appendix E – Study Budget:

Item	Description	Itemized Total
OPERATING EXPENSES:		
Salaries:	Principal and Co-Investigators	$40,000
	Lead Site Research Manager	$20,000
	Lead Site Study Coordinator	$20,000
	Participating site local research coordinators	$7,500 per participating study site (4 sites total) per year (2 years) = $60,000
CAPITAL EXPENSES:		
Equipment:	Virtual Reality Oculus Meta Quest 3 Devices (2 devices per site = 10 total)	$8000
	VR Attachments	$500
	Tripp Application Yearly Subscription (for 2 years)	$1,200
	Tablets (1 per VR device = 10 tablets total)	$4000
	Grand Total	**$153,700**

Funded awards:

Name of Award	Amount Awarded	Budgeted Items
SCCR (lead site) Canadian Neuromuscular Disease Registry Grant	$60,000	$7,500 per site (4 sites total) for 2 years to be used by local researchers to complete device training with participants, data collection and data transfer to the host site = $60,000-$7,500 (see Chesley Award below) = $52,500
In-Kind Contribution	$48,000	Principal and Co-Investigators time ($40,000), Clinical Research Manager Time ($20,000) $10,000 per year for a lead site study coordinator for 2 years ($20,000) Data Sharing Agreements prepared by Horizon Health Budgets and Contracts Manager ($5,000) Waiver of REB fees at Host Site for Investigator-Led Trial ($3,000)
Chesley Family Research Award	$25,000	Study equipment ($12,500) Salary of local researcher at 1 site for 1 year ($7,500) Knowledge Translation - Open Access Publication and National/International Conference Dissemination = $5,000
Rehabilitation Program Endowment Grant (QEII Foundation)	$1,309.33	One set of equipment costs (VR, attachments, tablet, app) for the Nova Scotia study site received by one of the co-investigators