

Principles and Practice of Clinical Research

A Global Journal in Clinical Research



PPCR

ISSN: 2378-1890

Protocol for a phase II, multicenter, open label, randomized controlled trial to compare the efficacy of gamification using Nintendo Switch Ring Fit Adventure game versus standard exercise in the treatment of fibromyalgia

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Received June 9, 2021; accepted August 5, 2021; published August 15, 2021.

DOI: <http://dx.doi.org/10.21801/ppcrj.2021.72.4>

APPENDICES

Appendix A – Adherence Questionnaire

1. How many days did you exercise this week? (options for marking: one, two, three, more than three, or none).
2. How long did the exercise last in minutes? (options for marking: less than 20 minutes, between 20-30 minutes, between 30-40 minutes, between 40-50, 60 minutes)
3. Rate the difficulty in performing the exercise (low, moderate to low moderate, moderate to high, high, and almost unbearable).
4. Did you experience any symptoms after the workout? (options: yes or no). If the answer is yes, list your symptoms.
5. If you could not do the exercise, please email the reasons for which this could not be done (increase of pain, no time for exercise, apathy, others)

Appendix B - Revised Fibromyalgia Impact Questionnaire (FIQR)

The Revised Fibromyalgia Impact Questionnaire

Domain 1 directions: For each of the following nine questions, check the one box that best indicates how much your fibromyalgia made it difficult to do each of the following activities over the past 7 days:

Brush or comb your hair	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Walk continuously for 20 minutes	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Prepare a homemade meal	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Vacuum, scrub, or sweep floors	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Lift and carry a bag full of groceries	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Climb one flight of stairs	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Change bed sheets	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Sit in a chair for 45 minutes	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult
Go shopping for groceries	No difficulty <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very difficult

Domain 2 directions: For each of the following two questions, check the one box that best describes the overall impact of your fibromyalgia over the past 7 days:

Fibromyalgia prevented me from accomplishing goals for the week	Never <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Always
I was completely overwhelmed by my fibromyalgia symptoms	Never <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Always

Domain 3 directions: For each of the following 10 questions, check the one box that best indicates the intensity of your fibromyalgia symptoms over the past 7 days:

Please rate your level of pain	No pain <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Unbearable pain
Please rate your level of energy	Lots of energy <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> No energy
Please rate your level of stiffness	No stiffness <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Severe stiffness
Please rate the quality of your sleep	Awoke rested <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Awoke very tired
Please rate your level of depression	No depression <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very depressed
Please rate your level of memory problems	Good memory <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very poor memory
Please rate your level of anxiety	Not anxious <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very anxious
Please rate your level of tenderness to touch	No tenderness <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Very tender
Please rate your level of balance problems	No imbalance <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Severe imbalance
Please rate your level of sensitivity to loud noises, bright lights, odors, and cold	No sensitivity <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Extreme sensitivity

Scoring: Step 1. Sum the scores for each of the three domains (function, overall, and symptoms). Step 2. Divide domain 1 score by three, divide domain 2 score by one (that is, it is unchanged), and divide domain score 3 by two. Step 3. Add the three resulting domain scores to obtain the total Revised Fibromyalgia Impact Questionnaire score.

Appendix C – Brief Pain Inventory

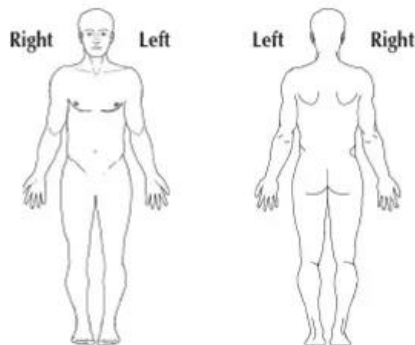
BRIEF PAIN INVENTORY

Date ____/____/____ Time: _____

Name: _____
Last First Middle Initial

- Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?
 1. Yes 2. No

- On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



- Please rate your pain by circling the one number that best describes your pain at its WORST in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

- Please rate your pain by circling the one number that best describes your pain at its LEAST in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

- Please rate your pain by circling the one number that best describes your pain on the AVERAGE.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

- Please rate your pain by circling the one number that tells how much pain you have RIGHT NOW.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

- What treatments or medications are you receiving for your pain?

- In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that shows how much RELIEF you have received.

0% 10 20 30 40 50 60 70 80 90 100%
 No relief Complete relief

- Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General activity

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

C. Walking ability

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

D. Normal work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
 Does not interfere Completely interferes

Brief Pain Inventory (Short Form). Source: Pain Research Group, Department of Neuro-Oncology, The University of Texas MD Anderson Cancer Center. Used with permission. Adapted to single page format. Copyright 1991 Charles S. Cleeland, Ph.D.

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Appendix D - The Beck Depression Inventory II



Beck Depression Inventory

Baseline

V 0477

CRTN: _____ CRF number: _____ Page 14 patient initials: _____



Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

<p>1. Sadness</p> <p>0 I do not feel sad.</p> <p>1 I feel sad much of the time.</p> <p>2 I am sad all the time.</p> <p>3 I am so sad or unhappy that I can't stand it.</p> <p>2. Pessimism</p> <p>0 I am not discouraged about my future.</p> <p>1 I feel more discouraged about my future than I used to be.</p> <p>2 I do not expect things to work out for me.</p> <p>3 I feel my future is hopeless and will only get worse.</p> <p>3. Past Failure</p> <p>0 I do not feel like a failure.</p> <p>1 I have failed more than I should have.</p> <p>2 As I look back, I see a lot of failures.</p> <p>3 I feel I am a total failure as a person.</p> <p>4. Loss of Pleasure</p> <p>0 I get as much pleasure as I ever did from the things I enjoy.</p> <p>1 I don't enjoy things as much as I used to.</p> <p>2 I get very little pleasure from the things I used to enjoy.</p> <p>3 I can't get any pleasure from the things I used to enjoy.</p> <p>5. Guilty Feelings</p> <p>0 I don't feel particularly guilty.</p> <p>1 I feel guilty over many things I have done or should have done.</p> <p>2 I feel quite guilty most of the time.</p> <p>3 I feel guilty all of the time.</p>	<p>6. Punishment Feelings</p> <p>0 I don't feel I am being punished.</p> <p>1 I feel I may be punished.</p> <p>2 I expect to be punished.</p> <p>3 I feel I am being punished.</p> <p>7. Self-Dislike</p> <p>0 I feel the same about myself as ever.</p> <p>1 I have lost confidence in myself.</p> <p>2 I am disappointed in myself.</p> <p>3 I dislike myself.</p> <p>8. Self-Criticalness</p> <p>0 I don't criticize or blame myself more than usual.</p> <p>1 I am more critical of myself than I used to be.</p> <p>2 I criticize myself for all of my faults.</p> <p>3 I blame myself for everything bad that happens.</p> <p>9. Suicidal Thoughts or Wishes</p> <p>0 I don't have any thoughts of killing myself.</p> <p>1 I have thoughts of killing myself, but I would not carry them out.</p> <p>2 I would like to kill myself.</p> <p>3 I would kill myself if I had the chance.</p> <p>10. Crying</p> <p>0 I don't cry anymore than I used to.</p> <p>1 I cry more than I used to.</p> <p>2 I cry over every little thing.</p> <p>3 I feel like crying, but I can't.</p>
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Continued on Back

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NR15645



Beck Depression Inventory

Baseline

V 0477

CRTN: _____ CRF number: _____ Page 15 patient inits: _____

11. Agitation

- 0 I am no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I am so restless or agitated that it's hard to stay still.
- 3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people or activities.
- 1 I am less interested in other people or things than before.
- 2 I have lost most of my interest in other people or things.
- 3 It's hard to get interested in anything.

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have much greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

- 0 I have not experienced any change in my sleeping pattern.
- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.
- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.
- 3a I sleep most of the day.
- 3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 I have not experienced any change in my appetite.
- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.
- 2a My appetite is much less than before.
- 2b My appetite is much greater than usual.
- 3a I have no appetite at all.
- 3b I crave food all the time.

19. Concentration Difficulty

- 0 I can concentrate as well as ever.
- 1 I can't concentrate as well as usual.
- 2 It's hard to keep my mind on anything for very long.
- 3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of the things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

3 4 5 6 7 8 9 10 11 12 A B C D E

Subtotal Page 2
 Subtotal Page 1
 Total Score

NR15645