Novel Use of ACT Techniques in a Home Physical Activity Intervention for Cognitive Late Effects in Children Treated with Radiation for Brain Tumors: Descriptive Feasibility Data from a Pilot Randomized Controlled Trial

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Background

- **Cranial radiation therapy (CRT)** for pediatric brain tumors contributes to cognitive late effects such as declines in IQ and impairments in specific domains (attention, memory, processing speed), which can affect academic functioning, daily living activities, and quality of life.
- Effective cognitive rehabilitation interventions are limited and need to be developed.
- Animal and human studies indicate **moderate-to-vigorous physical activity (MVPA)** positively impacts the same brain mechanisms (hippocampus, white matter) and cognitive functions damaged by CRT.
- Studies are needed to develop and evaluate interventions to increase MVPA and promote lifestyle change for improving cognitive late effects in pediatric brain tumor survivors.
- We incorporated aspects of **Acceptance and Commitment Therapy (ACT)** in a home **physical activity (PA)** intervention to facilitate changes in behavior to increase MVPA.

Objective

- To conduct a pilot **randomized controlled trial (RCT)** to evaluate the feasibility and preliminary efficacy of a home **physical activity (PA)** intervention on cognitive functioning in children treated with CRT for brain tumors.
- To examine descriptive feasibility data regarding the use of ACT techniques as part of the intervention to promote engagement in physical activity.

Methods

Eligible Participants

- Children 8-17 years, ≥ two years post-CRT for a brain tumor with cognitive late effects

Study Procedures

- After screening, enrolled children are randomized to either:

1) **Immediate Intervention Group (IIG)** Follows a 12-week home program to increase PA then maintains PA for the 2nd 12 weeks

2) **Delayed Intervention Group (DIG/control)** Monitors usual PA for 12 weeks (control period) followed by the 12-week home PA program

- Both groups underwent a fasting blood draw (to measure circulating growth factors), fitness treadmill test, and cognitive assessment before and after the 1st 12 weeks
- Brief cognitive assessment repeated after treadmill test and the 2nd 12 weeks

Measures

- MVPA: PA measurement using Zamzee accelerometers (minutes of MVPA per week)
- Cognitive Evaluation: Cogstate computerized battery of tests assessing processing speed, attention, visual memory/ learning, working memory, and executive function
- Fitness Evaluation: Modified metabolic stress treadmill exercise test

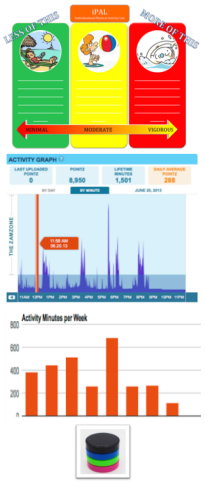
Physical Activity Program

Part 1: Educational session at NIH Clinical Center

- Learn about MVPA and choose MVPA activities to do
- Learn how to use the Zamzee activity tracker and website
- Participate in **Acceptance & Commitment Training (ACT)**

Part 2: Physical Activity Program at Home

- Increase PA to meet specific goals each week
- Upload PA data to website several times a week
- Receive weekly text messages and ACT emails
- Review progress, try challenges, earn points, buy rewards



Acceptance and Commitment Training Session

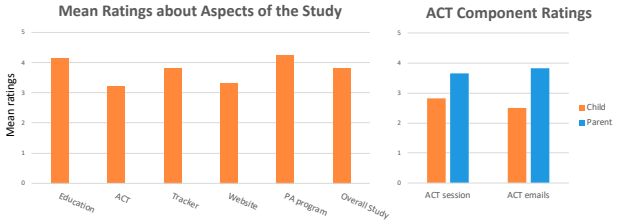
- 1.5 hour session at the NIH Clinical Center
- Parent and child meet together with trained investigator
- Complete worksheets and do practical exercises
- Home program: weekly emails to review techniques and practice skills; dictionary of ACT terms; monthly calls
- ACT Topics (focused on PA):
  - Discuss values related to PA
  - Set short, medium, and long-term PA goals
  - Problem-solve barriers that might get in the way of PA
  - Introduce and practice mindfulness
  - Discuss how acceptance (e.g., of discomfort while doing PA) can help us reach goals
  - Discuss how to defuse from thoughts that don't support PA
  - Make a commitment to doing more PA
  - Engage others

Feasibility Results

Demographic and Descriptive Characteristics of the Sample

Patient Number	Age (years)	Parent Education (years)	Diagnosis	Age at Diagnosis (years)	Time since Radiation (years)	Time since Diagnosis (years)
Immediate Intervention Group (n=3)						
1001	17	18	Medulloblastoma	2	15	15
1002	17	16	Craniopharyngioma	6	10	11
1003	17	15	Cranial Teratoma	10	6	7
Delayed Intervention Group (n=3)						
2001	14	14	PNET	9	4	5
2002	10	14	Cranial Teratoma	6	4	4
2003	17	12	Germinoma	10	7	7

Child and Parent Feedback about Aspects of the Study



- On 5-point Likert scales (1=none; 5=a lot), child and parent participants rated various aspects of the study
- Highest child and parent combined mean ratings: the education session at the NIH (mean=4.16) and overall satisfaction with the results of the home PA program (mean=4.25)
- Lowest child and parent combined mean ratings: ACT component (3.21) and Zamzee website (3.33)
- The individual ACT components were rated higher by the parents than by the children
- In open-ended questions, participants provided mostly positive comments
- We used the constructive feedback to modify the program, particularly the ACT component

Reported Use of ACT Techniques on the Feasibility Questionnaire

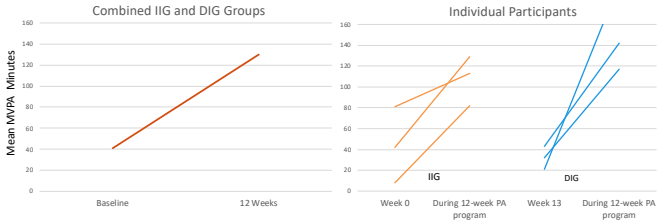
Frequency of ACT Techniques Used	Child-reported (n)	Parent-reported (n)
0 to ≤1 per week	3	3
2-3 x per week	2	0
3-4 x per week	1	3
>5 x per week	0	0

Type of ACT Techniques Used	Child-reported (n)	Parent-reported (n)
Think about values	2	2
Set goals	4	4
Use mindfulness	2	1
Use defusion	1	0

- At least half the participants reported using ACT techniques infrequently
- ACT techniques used most often were setting goals, thinking about values, and mindfulness

Preliminary Efficacy

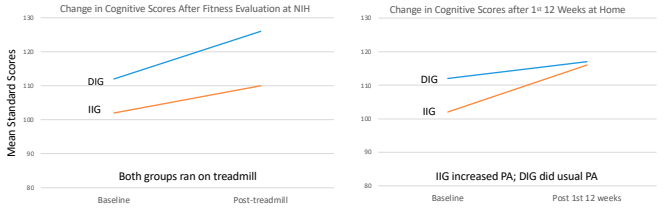
Increase in MVPA During the 12-week Physical Activity Intervention



- 100% of participants (6/6) increased their MVPA across the PA intervention period; total baseline week mean=41 min; during intervention (4, 8, & 12 weeks) total mean=130 min
- IIG: Baseline week mean=43 min; during intervention (4, 8, & 12 weeks) total mean=107 min
- DIG: Baseline week mean=38 min; during intervention (16, 20, & 24 weeks) total mean=152 min

Preliminary Efficacy

Change in Primary Cognitive Outcome (Cogstate Visual Memory Scores)



- After acute PA on the treadmill (20 min), 5/6 participants had improved Cogstate visual memory scores (normative mean=100; SD=15); total means=107 at baseline to 118 post-treadmill.
- After 1st 12 weeks at home, IIG showed greater increase in visual memory scores after the 12-week PA intervention compared to after the DIG 12-week control period of usual activity (14 vs. 5 points).

Pros, Cons, and Changes Based on Initial Feasibility Data

Initial PA Program

Pros:

- Child-friendly program
- Participants liked using an activity tracker
- Website was fun, easy to navigate and upload data, and showed graphs to track MVPA
- Goal-setting was used my most participants
- Participants were motivated by the Zamzee rewards

Cons:

- ACT components were lowest rated and used infrequently by most participants
- Weekly ACT emails were too long to read
- Activity monitors were lost, washed, or broken
- Zamzee terminated their products in July 2015 forcing a change to a new activity tracker

Updated PA Program

- Different activity tracker by Polar, which is waterproof and worn on the wrist, and website
- Developed videos to provide weekly ACT exercises at home
- Developed child-friendly ACT workbook to take home
- Reworked parts of the ACT session to link the session topics with the ACT workbook; discuss ACT more on the calls

Summary

- Pilot data generally indicates good feasibility of the home PA intervention:
  - All children completed all three evaluations and followed home guidelines to increase PA
  - Children and parents reported positive feedback about the PA program and found it helpful
- ACT component feasibility:
  - ACT component was rated lower than other aspects; techniques used infrequently by most
  - Goal-setting was the main ACT technique used by most participants to help increase MVPA
- Preliminary efficacy data is promising:
  - All children increased their minutes of MVPA during the intervention
  - Primary cognitive outcome scores increased with exercise (post in-lab treadmill & home intervention) suggesting potential benefit in pediatric brain tumor survivors
- Lessons learned:
  - Children may need simple, interactive methods (e.g., ACT videos vs. emails) to be more engaged and additional time discussing use of ACT during monthly calls
  - Use of e-health tools is feasible, but rapid changes in technology may limit continuity
- Physical activity could offer a much-needed cognitive rehabilitation intervention for pediatric brain tumor survivors; more specifically, using ACT techniques may help promote long-term behavior change and facilitate integrating exercise into their daily lives at home; **a full RCT is actively recruiting to evaluate this revised PA intervention program**

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