FITing a BIT of Consumer-Based Technology Into Patient Management

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Background

Many single ventricle congenital heart diseases are palliated through a set of surgeries, ending in the Fontan procedure. Regular exercise can improve exercise capacity and is increasingly recognized as safe in this population. With the increasing popularity of consumer-based activity monitors such as "Fitbit", it is important to explore the idea that giving patients a device is a way to get them engaged in exercise and monitor heart activity from an outpatient management standpoint.

Methods

We prospectively studied the compliance with Fitbit activity monitoring in a cohort of 19 prospectively enrolled adolescents after Fontan palliation. Subjects were seen in clinic between November 2018 and April 2019 and received a Fitbit Blaze device which was to be worn as continuously as possible for 3 months. Fitbit-wearing compliance was measured by looking at daily resting heart rate data. At the completion of the 3 months, subjects were asked to complete a questionnaire to evaluate their acceptance of the devices and to gauge their interest in using technology to augment their outpatient medical care.

Technology

The devices were set up to synch automatically and wirelessly to a computer or smartphone using Bluetooth technology. Data was reviewed and monitored frequently through the "*fitabase*" data platform which depicted the study participants' resting heart rate, pule, oxygen saturations.

Objectives

The study will examine if adolescents who have undergone the Fontan operation will accept the use of activity monitors on a daily basis and whether or not these devices provide meaningful data.

The primary objective is to see if using activity monitors would be feasible in the outpatient management of Fontan patients

The secondary objective is to asses the acceptability of integrating technology into patient care

Schedule of Study Procedures

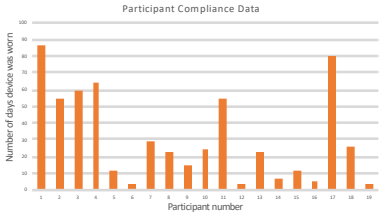
Study Phase	Screening	Initial Study Visit	Study Completion Visit
Visit Number		**1**	**2**
Review of medical records to determine eligibility for study enrolment	X		
Informed Consent/Assent		X	
Physical Examination		X	X
Vital Signs: BP, HR, RR		X*	X
Height and Weight		X*	X
Set Up and Disperse Activity Monitors		X*	
Demographic data collection		X*	
Questionnaire completion			X

Demographic Data and Questionnaire

Participant PID:	
Date of birth	
Race	
Cardiac diagnosis	
Medications	
Co-morbidities	
Gender	
Weight/Height/BMI	
Echocardiographic data	
Date of Fontan and type of Fontan	

Survey question	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
I enjoyed wearing the fitness device	1	2	3	4	5
The Fitbit was not too easy to use	1	2	3	4	5
I was more active than usual when wearing the monitor	1	2	3	4	5
Wearing the monitor made me feel anxious.	1	2	3	4	5
I will continue to use the monitor now the study is over	1	2	3	4	5
I am interested in using a smart phone application to communicate with my cardiologist	1	2	3	4	5
I am interested in using a smart phone application to transmit activity data to my cardiologist	1	2	3	4	5

Results

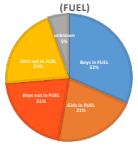


Patient number	% compliance
1	93.54%
2	58.06%
3	63.44%
4	68.81%
5	12.08%
6	3.29%
7	31.87%
8	24.18%
9	16.48%
10	26.37%
11	59.34%
12	3.30%
13	24.18%
14	7.69%
15	12.09%
16	5.56%
17	88.89%
18	27.96%
19	4.30%

Patient Number	Height	Weight	Date of Consent	FUEL or Not FUEL	Gender
1	160	50.8	11/8/18	FUEL	Female
2	170.2	61.7	11/12/18	FUEL	Male
3	6/23/00	3/12/00	11/16/18	FUEL	Male
4	166	44.9	11/30/18	FUEL	Male
5	171.6	53.9	12/6/18	FUEL	Male
6	159	44.9	12/7/18	FUEL	Male
7	145	47.1	12/13/18	Not FUEL	Female
8	155	47.7	12/18/18	Not FUEL	Female
9	172	50.8	12/20/18	Not FUEL	Male
10	165.1	53.9	12/27/18	Not FUEL	Female
11	173.5	60.7	12/28/18	FUEL	Male
12	169.9	54	1/3/19	Not FUEL	Female
13	142.5	36.2	1/10/19	Not FUEL	Male
14	140	30.1	1/24/19	Not FUEL	Male
15	166.4	49.8	1/31/19	Not FUEL	Male
16	157.8	48.6	2/11/19	FUEL	Female
17	163.5	53.6	2/21/19	FUEL	Female
18	196.6	68.3	3/1/19	FUEL	Female
19	159.1	54.3	4/18/19	UNKNOWN	Female

Summary of Dara	
Average Age	15 (σ = 1.66)
Average Weight	51.78 (σ = 9.9)
Average Height	163.6 cm (σ = 13)
Active Participation (compliance >50%)	26%
Continuous Participation (compliance > 75%)	10.5%
% male	52.6%
% female	47.4%

PERCENTAGE OF PARTICIPANTS IN AN CONCOMITANT EXCERSIZE-RELATED STUDY (FUEL)



FUEL was an adjacent study under a different PI and study coordinator that also involved an exercise component. Many participants who were enrolled in FUEL also chose to enroll in this Fitbit study. FUEL provided its participants with a more regimented and personalized exercise plan which seemed to generally (but not always) correlate with better compliance in the Fitbit monitor study.

Conclusion

Unprompted compliance with a Fitbit activity monitor in a cohort of adolescent patients after Fontan was quite poor. While ambulatory monitoring may be a useful adjunct to exercise training programs, the mere presence of the device does not appear to be sufficient to motivate this cohort to be compliant, at least without prompting. Perhaps if a Fitbit was given to Fontan subjects, it would be beneficial if it were tied to another training program. More work is needed to understand the role of ambulatory activity monitors in comprehensive wellness programs for this cohort of patients.

Future Plans

Further study should include an exercise regimen or training program in conjunction with the FitBit to improve compliance and thereby become a more realistic tool in the outpatient management of Fontan patients. Future studies should also aim to understand the importance of goals, feedback and incentives to affect behavioral change with behavioral devices. Finally, future studies should also aim to receive feedback from all participants.

Acknowledgments

Supported in part by the Cardiac Center at the Children's Hospital of Philadelphia.

Special thanks to David Goldberg, MD for acting as Principal Investigator and Catherine Avitabile, MD, for her guidance and support

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