Real-World Continuous Physiologic Monitoring in Pediatric Cardiomyopathy Patients: A Safety and Feasibility Study

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CHOP Cardiology, 2018

Children's Hospital of Philadelphia℠
Cardiac Center

ANCC MAGNET RECOGNITION

Cardiology 2018

Background

- Cardiomyopathy
  - Associated with significant morbidity, mortality, and cost.
  - Medical advances=> outpatient management and improved heart failure outcomes
  - Psychosocial, physical, and financial stressors remain

Background

- Limited ability to predict serious adverse events in the pediatric cardiomyopathy population
- Historically, outpatient management has focused on activity restriction
- Determining level of activity that is healthy AND safe is challenging.

Purpose

- To examine the safety and feasibility of consumer based activity monitor use in outpatient management of pediatric cardiomyopathy patients

- To assess patient acceptance of technology integration into care

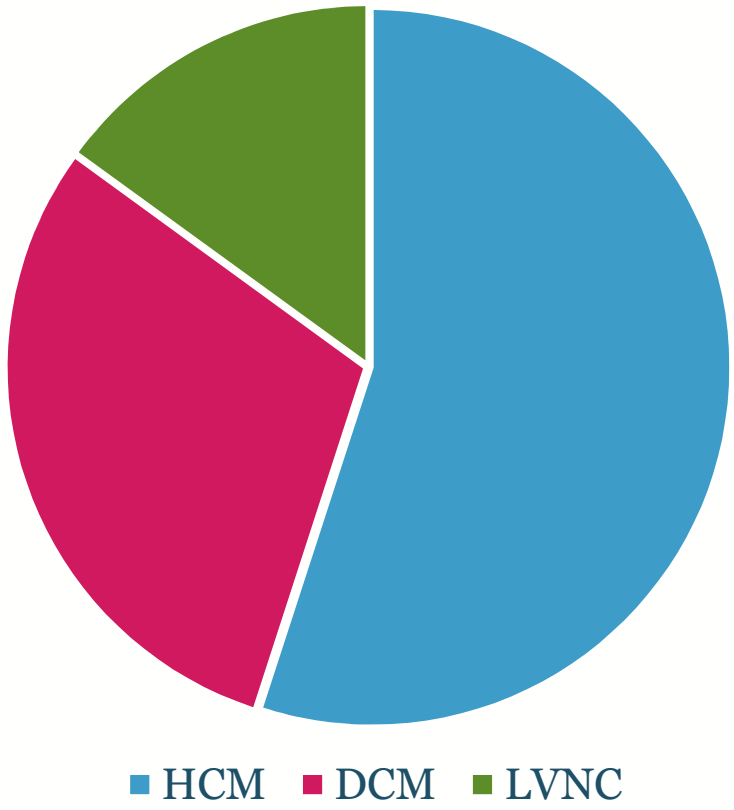
Study Design and Methods

- Pilot clinical trial, single center study
- 20 adolescent cardiomyopathy patients seen in a pediatric cardiomyopathy clinic between 10/2016-6/2017
- Study Device
  - Fitbit Blaze
  - Worn as continuously as possible for 3 months
- Data
  - Heart rate, activity, and sleep
    - Transmitted via Bluetooth into database (Fitabase)
  - Study completion questionnaires

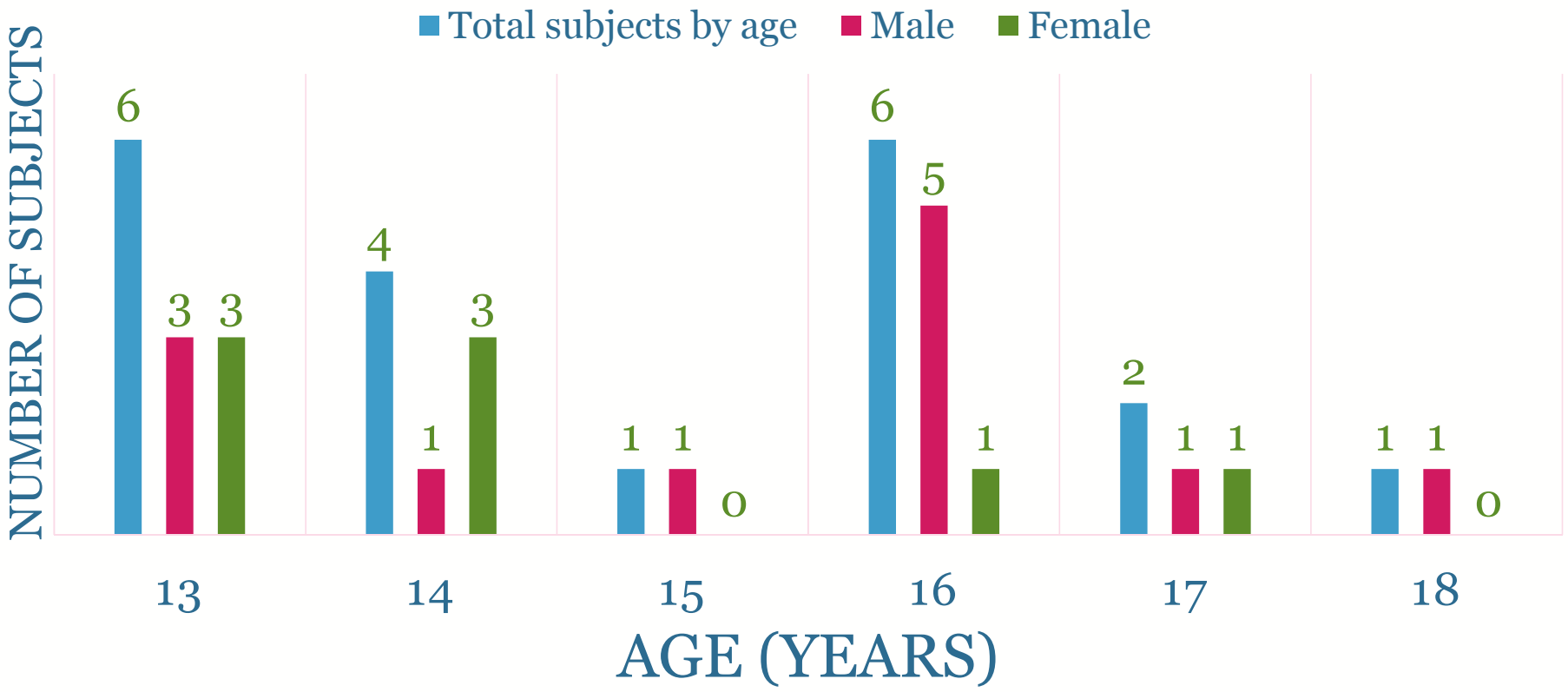
Subject Characteristics

- Between the ages of 13-18 at study enrollment
- Primary cardiomyopathy (HCM, DCM, LVNC, or RCM)
- Managed as an outpatient
- Access to a computer or smart phone for data transmission
- Parental/guardian permission and child assent to participate
- NOT listed for transplantation

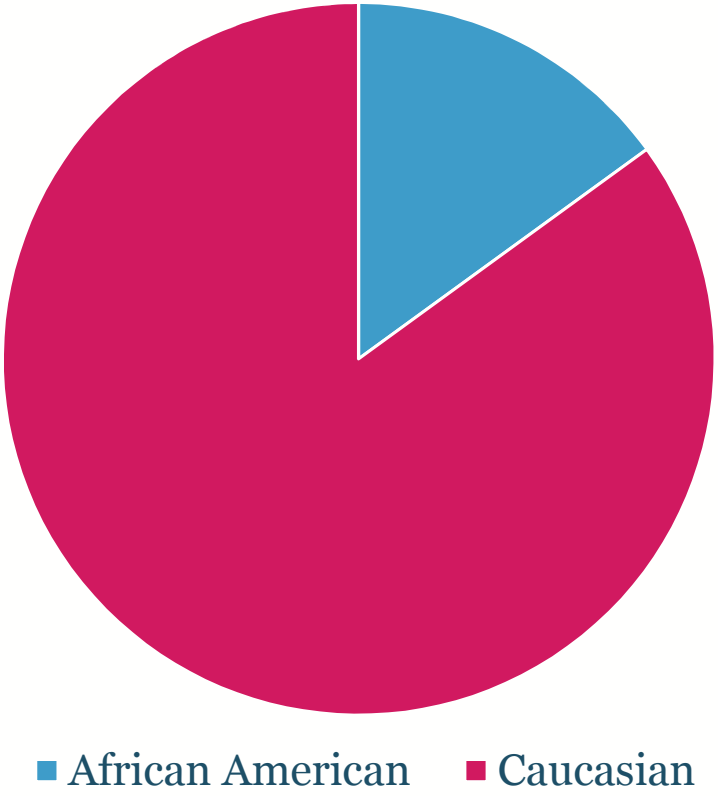
Subject Characteristics



Subject Characteristics



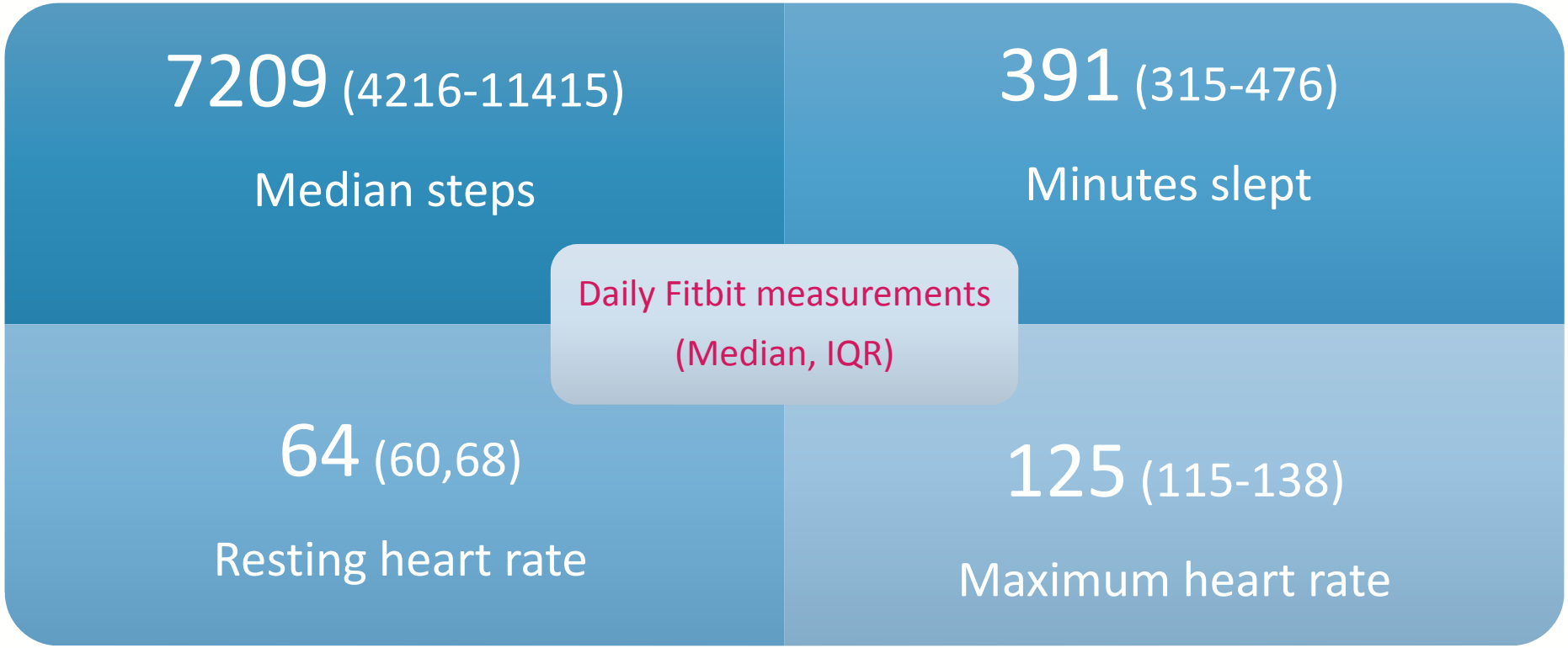
Subject Characteristics



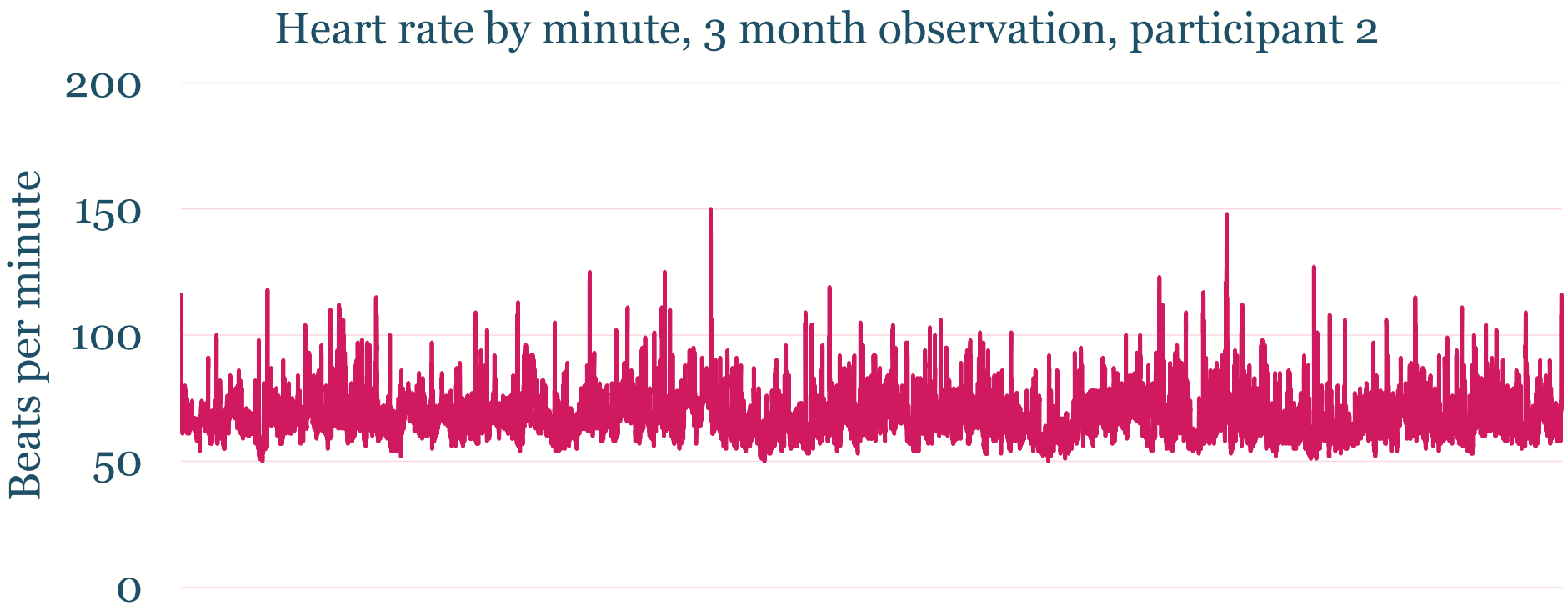
Results

- 19 subjects completed the study
  - 7 (37%) female
  - 12 (63%) male
  - Median age 14.9 years
- Devices were worn an average of 70 days over the 3-month study period, meeting criteria for consistent use
- No device related adverse events

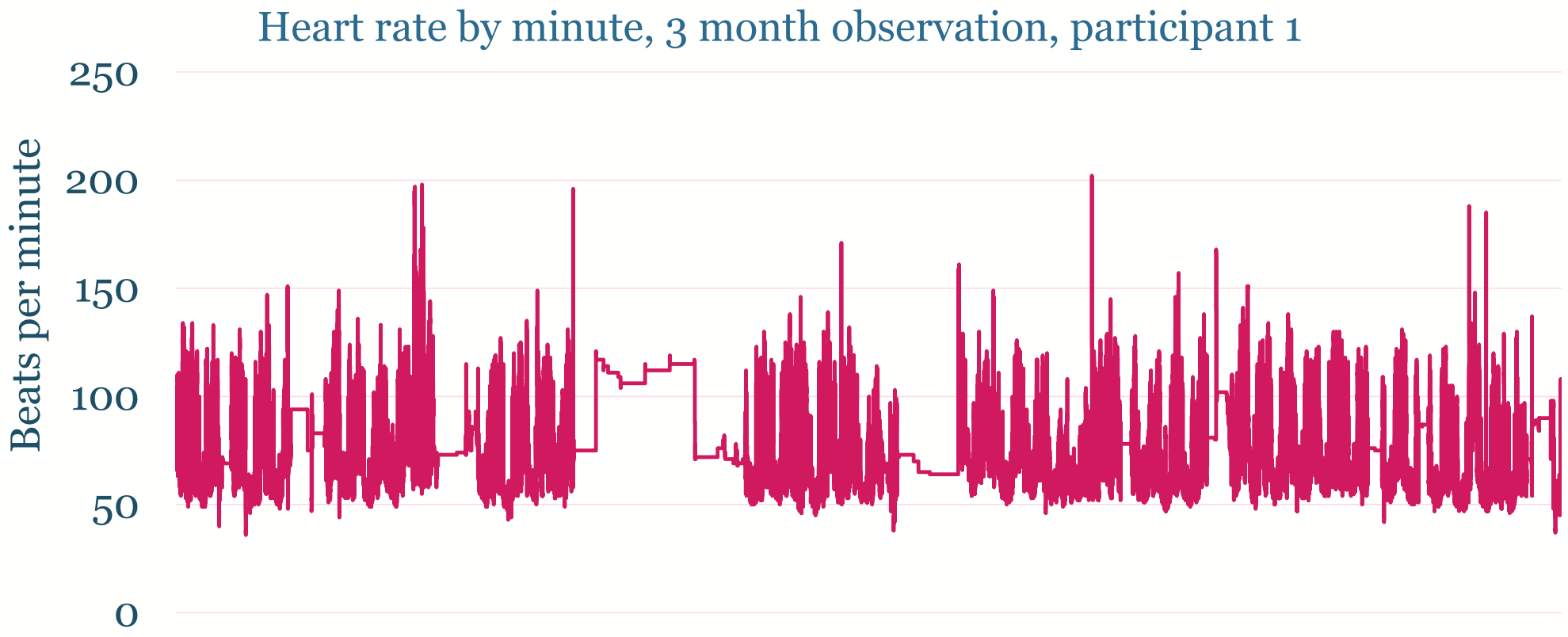
Results


7209 (4216-11415)
Median steps
391 (315-476)
Minutes slept
Daily Fitbit measurements
(Median, IQR)
64 (60,68)
Resting heart rate
125 (115-138)
Maximum heart rate

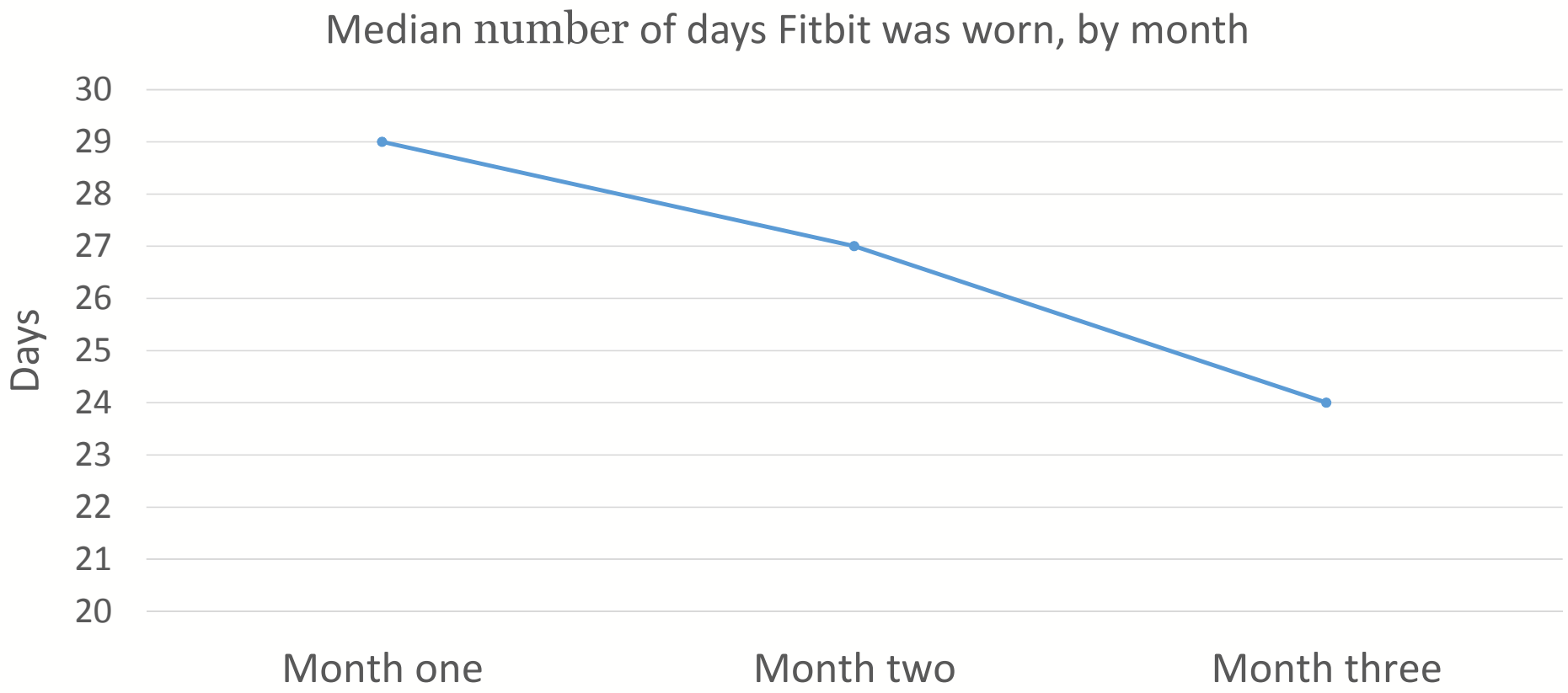
Results


Heart rate by minute, 3 month observation, participant 2
Beats per minute
200
150
100
50
0

Results


Heart rate by minute, 3 month observation, participant 1
Beats per minute
250
200
150
100
50
0

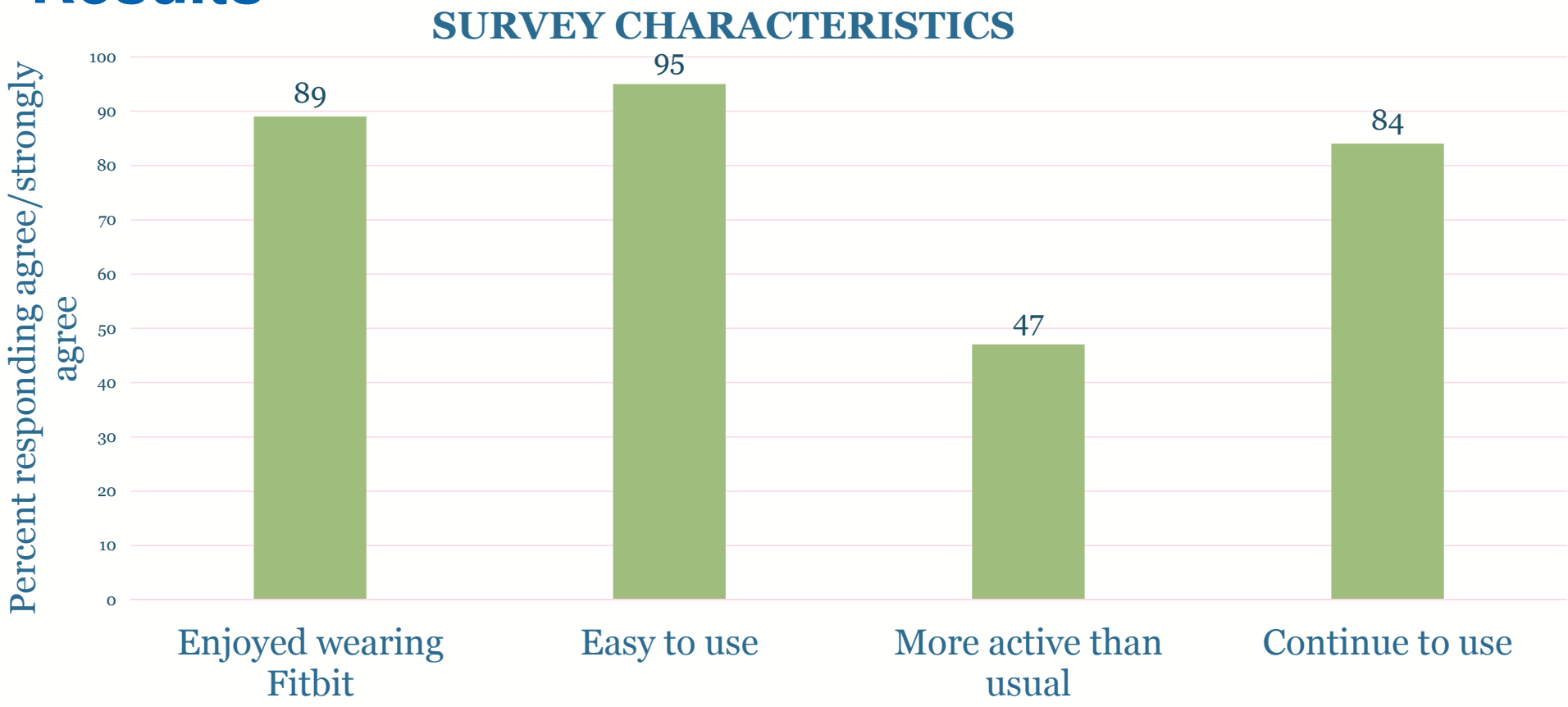
Results


Median number of days Fitbit was worn, by month
Days
30
29
28
27
26
25
24
23
22
21
20
Month one
Month two
Month three

Results

	1= strongly agree		2= agree		3= uncertain		4= disagree		5= strongly disagree	
	n	%	n	%	n	%	n	%	n	%
I enjoy wearing the Fitbit	8	42%	9	47%	2	11%	0	0%	0	0%
The Fitbit device was easy to use	16	84%	2	11%	1	5%	0	0%	0	0%
I was more active than usual when wearing the monitor	5	26%	4	21%	9	47%	1	5%	0	0%
Wearing the monitor made me feel anxious	1	5%	4	21%	5	26%	9	47%	0	0%
I will continue to use the monitor now that the study is over	7	37%	9	47%	2	11%	1	5%	0	0%
I am interested in using a smart phone application to communicate with my cardiologist	8	42%	6	32%	4	21%	1	5%	0	0%
I am interested in using a smart phone application to transmit activity data to my cardiologist	6	32%	10	53%	3	16%	0	0%	0	0%

Results


SURVEY CHARACTERISTICS
Percent responding agree/strongly agree
100
90
80
70
60
50
40
30
20
10
0
89
95
47
84
Enjoyed wearing Fitbit
Easy to use
More active than usual
Continue to use

Conclusions

- Use of a consumer based activity monitor is both safe and feasible
- Vast majority of study participants were interested in integrating technology into routine management
- This pilot study is the first step in working to define optimal disease management for this complex patient population in the age of consumer-driven healthcare
- We aim to use this data to support a large randomized trial

Thank You

The Cardiac Center at The Children's Hospital of Philadelphia

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