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DIGITAL HEALTH MONTHLY

SCIENTIFIC WEBINAR SERIES

Monitoring Activity and Gait in Children Using DHTs

May 21, 2024

June's Digital Health Monthly topic:
DHT 101 | Date: TBD

Digital health and pediatric clinical research

Challenging the status quo

- Inequities in pediatric digital health, suggesting that innovation and investment in children are lagging.
- As healthcare becomes increasingly digital—augmented by digital devices, and backend AI—it's important that digital tools keep pediatric care stakeholders in mind.
- There is a noticeable trend toward greater use of digital health solutions in pediatric care.
- The increasing adoption of these technologies signals a move toward more comprehensive and convenient care for children to enhance health outcomes and patient experiences.

Rock Health Report, *Next gen innovation: Opportunities in pediatric digital health, Nov 20, 2023*

Monitoring Activity and Gait in Children Using DHTs

Featured Speaker

Junrui Di, PhD

Biostatistician

Pfizer Inc.

Monitoring Activity and Gait in Children Using DHTs

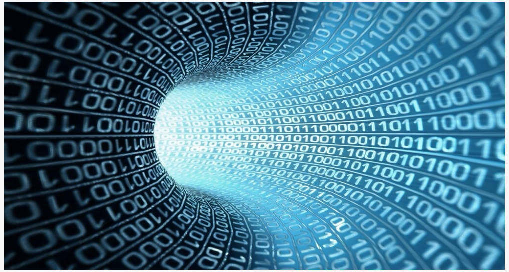
Junrui Di, on behalf of the Pfizer Innovation Research Lab

Biostatistician

Pfizer Inc.

Digital Health Technologies (DHTs) offer an opportunity to monitor the patients' health outcomes in their natural environment

Continuous, multimodal, unstructured data collection



Algorithm development (statistics & ML/AI)

New digital biomarkers of disease

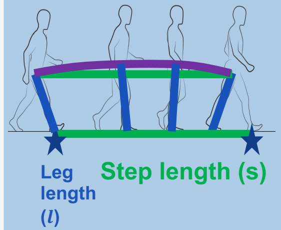
Gait and Physical Activity Impact Multiple Indications

Why measure gait and physical activity?

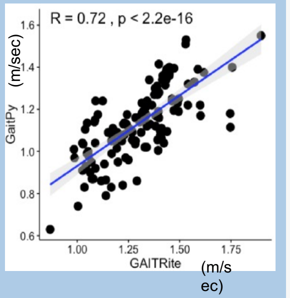
- Gait speed has been referred to as the **6th vital sign**, is a **surrogate marker** for mobility, and can predict survival, hospitalization & all-cause mortality in heart failure
- *95th **percentile stride velocity*** has been **qualified by EMA** as a primary endpoint for registration in DMD
- **Moderate to vigorous physical activity (MVPA) qualified by FDA** as primary endpoint for pivotal cardiopulmonary study

Scikit Digital Health Gait Module

Context Detection | Gait Feature Extraction



Validating gait speed

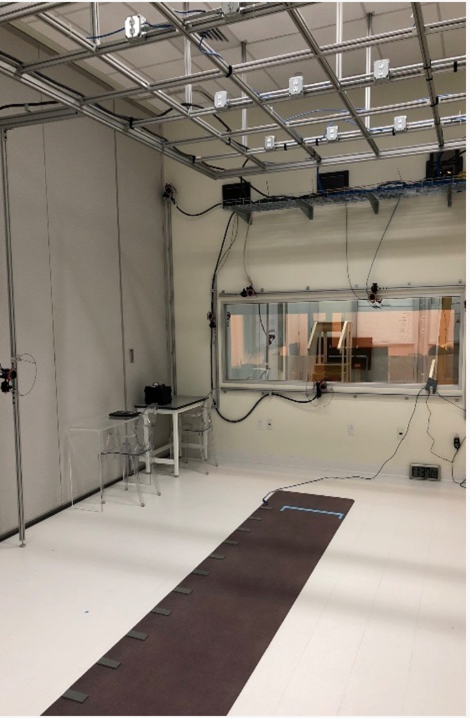


Czech et al., *Journal of Open Source Software* 2020
Adamowicz et al. JMIR mhealth and uhealth, 2022

TA Impact

- Duchenne Muscular Dystrophy
- Friedreich Ataxia
- Achondroplasia
- GLP1 Obesity/DM2
- ...

Pfizer Innovation Research Lab, Cambridge, MA



Where: The PfIRe Lab is a fully compliant, clinically approved space to conduct studies involving human participants.

What: Evaluate novel sensors and methods enabling digital data collection continuously, passively and remotely at home.

How: State-of-the-art, instrumented clinical environment to test digital sensors, compare data vs ”gold standards”, compare in clinic vs at home, and develop novel digital endpoints.

Gait and Physical Activity in Children
A need for technical validation

Monitoring Activity and Gait In Children (MAGIC)

- Gait has been studied in children across psychiatric, neurological, and motor diseases.
- PA has been studied in children for obesity, normal growth and development, cardiovascular risks etc.
- There remains a lack of standardized measures and further validation of DHTs in developing children.

Population: 3-17 year old pediatric healthy participants.

Design: Non-randomized, low interventional study recruiting 40 participants

Objectives:

* Validate the performance and feasibility of DHT-measured gait and physical activity in the pediatric population.

* Assess feasibility of recruiting pediatric participants,

* Evaluate compliance, and wearability/comfort with at home monitoring technology.

Study Design

PfIRe Lab

Visit 1
(Day 1)

At Home Monitoring
(Day 1- Day 15+3)

Follow-up Phone Interview
(Day 15 + 3 days)

Walking Tasks:
- Normal
- Fast
- Slow

Wearability/Comfort Questionnaire

- ActiGraph CP
  - Wrist
  - Lumbar
- Daily Activity Dairy

- Wearability/Comfort Questionnaire
- Assessment for AEs
- Instructed to mail back devices

Demography

- **Three age groups**
  - 3 – 5 y.o. N = 13
  - 6 – 11 y.o. N = 14
  - 12 – 17 y.o. N = 13
- **Age**: 9.38 (4.48) y.o.
- **BMI**: 18.86 (3.79)
- **Gender**: 22 (55%) Female
- **Race**: 26 (65%) White

Recruitment Feasibility

	3 – 5 y.o.	6-11 y.o.	12 – 17 y.o.	Total
	N = 13	N = 14	N = 13	N = 40
Number of Enrolled Patients Per Month				
Month 1	5	3	5	13
Month 2	2	6	5	13
Month 3	1	3	3	7
Month 4	0	2	0	2
Month 5	1	0	0	1
Month 6*	0	0	0	0
Month 7	1	0	0	2
Month 8	3	0	0	3

*COVID19 Winter Surge Peak 2021: study team paused recruitment briefly

The 3–5 years age group took the longest to recruit (232 days), and the shortest to recruit was the 12–17 years group (77 days).

Compliance in Wearing the Device At-Home

	3-5 y.o.	6 – 11 y.o.	12 – 17 y.o	Total
Wear Time Per Day in Hours - Wrist				
Wrist Mean (SD)	21.05 (2.46)	21.80 (1.947)	22.01 (2/169)	21.62 (2.178)
Lumbar Mean (SD)	7.24 (4.293)	12.51 (3.630)	14.24 (4.574)	11.36 (5.038)
Percentage of Compliant Days %				
Wrist Mean (SD)	81.79 (14.312)	88.94 (13.161)	87.07 (16.750)	86.01 (14.714)
Lumbar Mean (SD)	41.47 (30.910)	79.35 (25.11)	81.23 (14.609)	67.65 (30.174)

Compliant days were calculated as the number of days with equal or greater than:

- 10 hours of wear time for the lumbar device
- 18 hours of wear time for the wrist device

Comfort and Wearability

In-clinic

- 85% of the participants either **“agree” or “strongly agree”** that the wrist and lumbar DHTs were comfortable to wear
- There was no statistically significant difference between the total score of wrist and lumbar

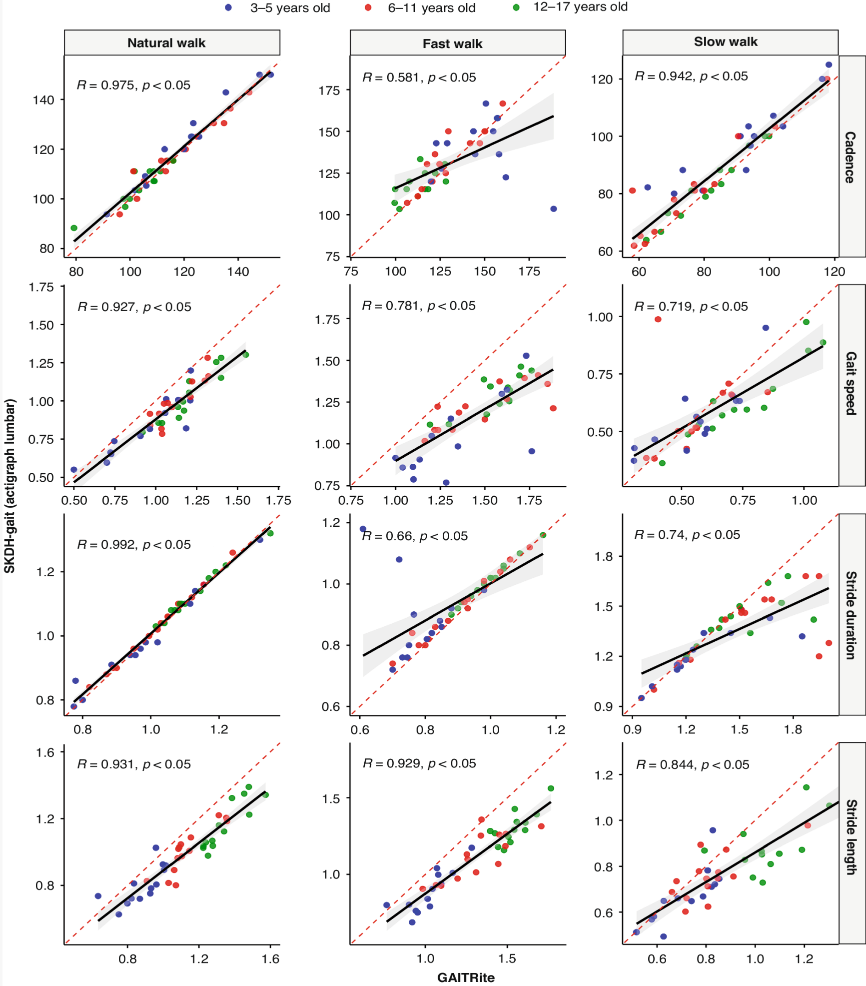
At-home

- 95% of the participants either “agree” or “strongly agree” that **wrist** DHTs were comfortable to wear
- only 72.5% of the participants either “agree” or “strongly agree” that the **lumbar** DHTs were comfortable to wear at home.
- 97.5% and 82.5% of the participants either “agree” or “strongly agree” that they were willing to wear the wrist and lumbar accelerometers for more than 7 days, respectively.
- The overall score for the wrist-worn DHTs was significantly higher than the lumbar DHTs.

In-lab Gait Validation

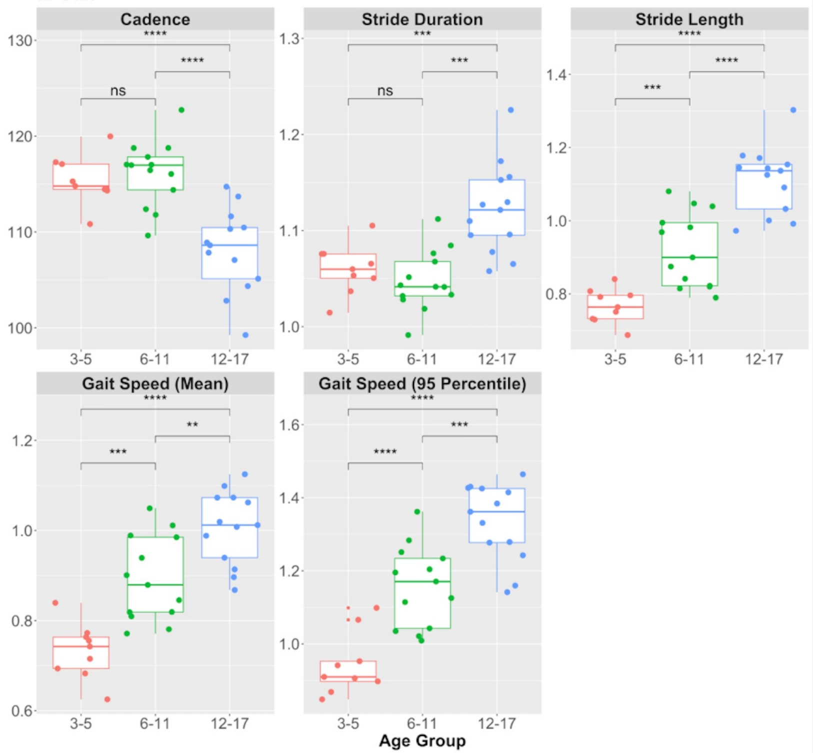
Intra-class correlation coefficients

	Natural Walk	Fast Walk	Slow Walk
Cadence	0.971 (0.94, 0.99)	0.578 (0.33, 0.75)	0.914 (0.60, 0.97)
Gait Speed	0.748 (-0.14, 0.95)	0.432 (-0.13, 0.82)	0.704 (0.50, 0.83)
Stride Duration	0.99 (0.98, 1.00)	0.623 (0.35, 0.79)	0.638 (0.29, 0.81)
Stride Length	0.773 (-0.16, 0.95)	0.697 (-0.12, 0.93)	0.721 (0.08, 0.90)

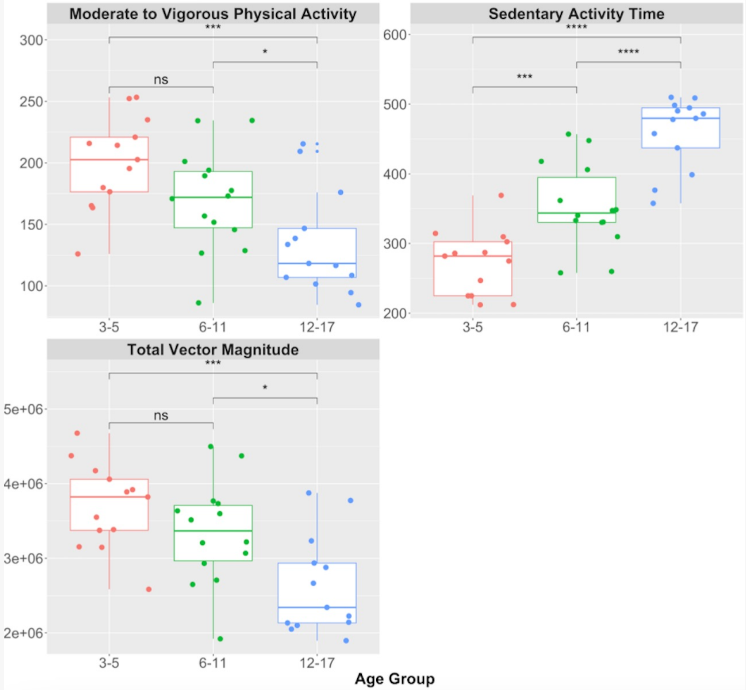


Age Effects on Gait and Physical Activity

Gait

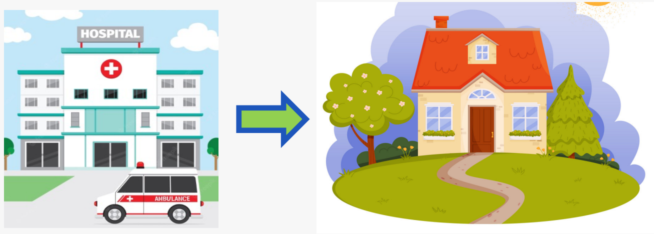


Physical Activity



Conclusion

- Gait and physical activity data can be collected from DHTs in pediatric populations, with both reliable accuracy and wear compliance both in-clinic and in home environments.
- The identified across-age-group differences in gait and activity measurements highlighted their potential clinical value.
- The use of DHTs enables trial sponsors to consider decentralized clinical trials which can reduce patients’ and parents’ burden and increase patients’ diversity.



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Monitoring Activity and Gait in Children (MAGIC) using digital health technologies

Junrui Di, Pirinka Georgiev Tuttle, Lukas Adamowicz, Wenyi Lin, Hao Zhang, Dimitrios Psaltos, Jessica Selig, Jiawei Bai, F. Isik Karahanoglu, Paul Sheriff, Vijitha Seelam, Bunmi Williams, Sana Ghafoor, Charmaine Demanuele, Mar Santamaria & Xuemei Cai

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Thank You for Your Time.

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Monitoring Activity and Gait in Children Using DHTs

Thank you!

Scan for Survey

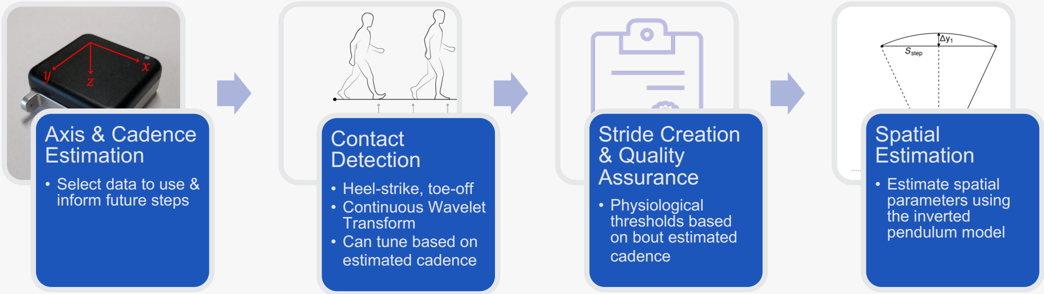
Back up

The Gait Module in SKDH

Lukas Adamowicz
Data Scientist

Algorithm Details

- **Lumbar accelerometer based**
- **Provides temporal (e.g. stride time) & spatial (e.g. stride length) gait metrics**
- Algorithm details:
  - Custom classifier detects gait bouts (3s windows)
  - Continuous wavelet transform (CWT) based initial/final contact detection (McCamley 2012)
  - Inverted pendulum model for spatial measures (Zijlstra 2003)
  - Quality check per step/strides:
- Computes signal-based asymmetry gait measures



Manual adjustment of parameters for some populations

Continuous Improvements

EMA DMD Gait Submission Construct Validity

Instances of poor spatial metric agreement

Can we make improvements to the gait algorithm?

Demography

	3-5 y.o N = 13	6 – 11 y.o. N = 14	12 – 17 y.o. N = 13	Total N = 40
Age (years)				
Mean (SD)	4.38 (0.65)	9 (1.8)	14.77 (1.59)	9.38 (4.48)
Gender, n (%)				
Female	7 (53.8)	6 (42.9)	9 (69.2)	22 (55)
BMI (kg/m^2)				
Mean (SD)	16.53 (1.94)	18.25 (3.81)	21.86 (3.34)	18.86 (3.79)
Race, n (%)				
White	8 (61.5)	10 (71.4)	8 (61.5)	26 (65)
Black	1 (7.7)	0	0	1 (2.5)
Asian	3 (23.1)	3 (21.4)	5 (38.5)	11 (27.5)
Multiracial	1 (7.7)	1 (7.1)	0	2 (5)