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The Joe and Linda Chlapaty
Stanford DECIDE Center

ENHANCE-AF

Clinical Trial to Evaluate an Atrial Fibrillation Stroke Prevention Shared Decision-making Pathway

Paul J Wang, MD (Center Director)
Randall Stafford, MD, PhD (Project Director)
Kenneth Mahaffey, MD (Dir Clinical Coordinating Center)
Ying Lu, PhD (Dir Data Coordinating Center; Statistician)
Amy Lin, MPH (Data Analyst)
Karma Lhamo (Project Manager)
Eli Rice (Project Manager)
Bryant Lin, MD, MSEng (Training Director)
Rushil Shah, MBBS, DNB, MHS (SFRN Fellow)

AHA SFRN Funded Research

Additional Co-authors

Daniel P Morin [1]
Samuel F Sears Jr. [2]
Mina K Chung [3]
Andrea M Russo [4]
Jonathan P Piccini [5]
Mellanie True Hills [6]
Caroline Berube [7]
Krishna Pundi [7]
Tina Baykaner [7]
Gotzone Garay [7]
Eli Rice [7]
Paul Newswanger [7]
KatieDeSutter [7]
Julio Nunes [8]
Michelle A Albert [9]
Kevin Schulman [7]
Paul A Heidenreich [10]
T J Bunch [11]
Lee Sanders [7]
Mintu Turakhia [7]

[1] Ochsner Univ Medical Center
[2] East Carolina University
[3] Cleveland Clinic
[4] Cooper Health
[5] Duke University Medical Center
[6] StopAfib.org
[7] Stanford School of Medicine
[8] Yale University
[9] University of California San Francisco
[10] Palo Alto VA HCS
[11] Univ of Utah School of Medicine

Our Patient

Mrs. Jones is a 79-year-old woman with hypertension and diabetes mellitus.

CHA_2DS_2-VASc score of 5,
7% annual stroke risk

Anticoagulation is recommended

Mrs. Jones declines

"I do not understand the stroke risk; bleeding risk must be higher."

Her satisfaction for the process is low.

Primary Problem

Current practices around stroke prevention in patients with atrial fibrillation lead to—


Lack of patient satisfaction


Therapy mismatched with patient preferences

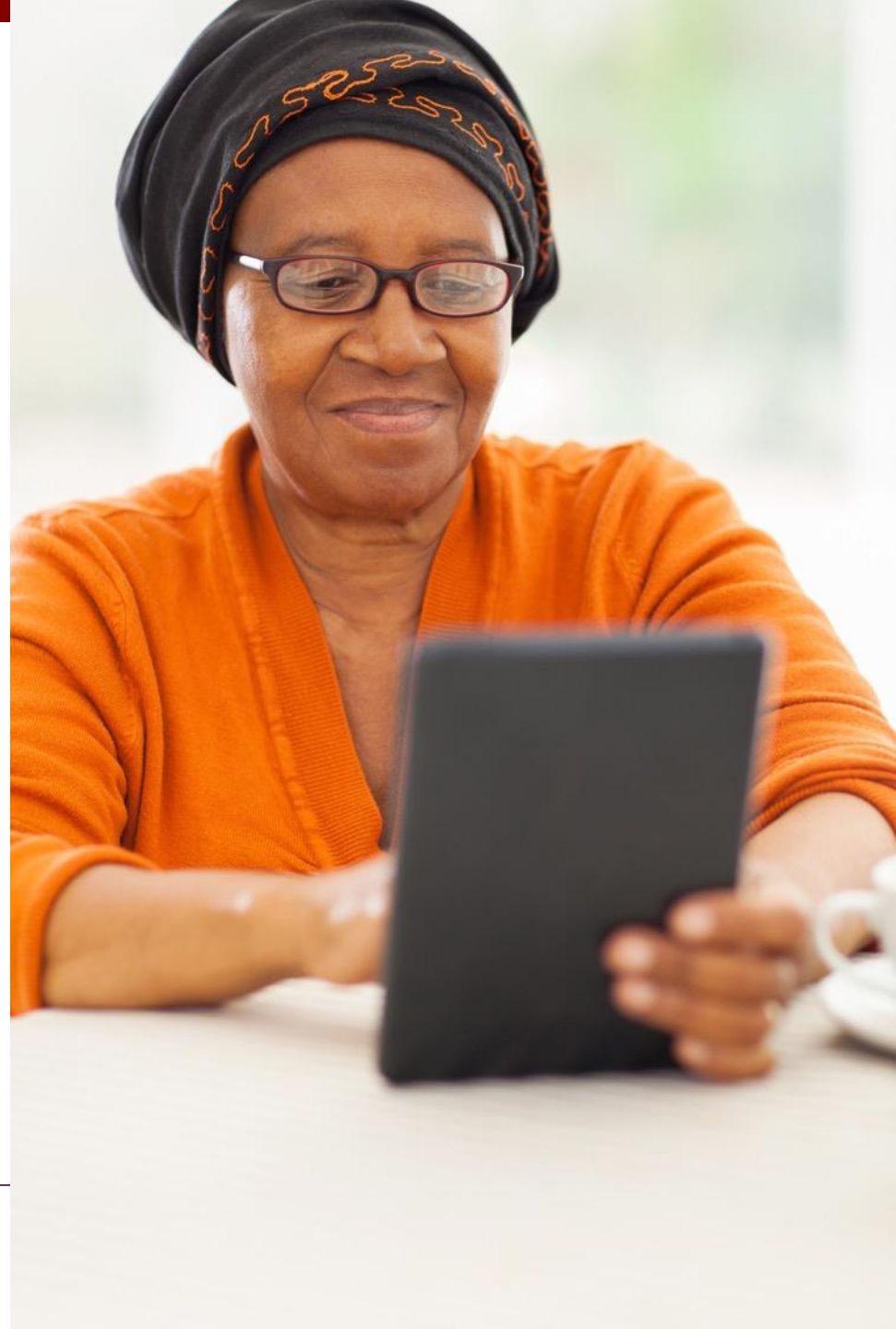

Wasted health care resources


Preventable adverse outcomes

Mrs. Jones: Future State

Mrs. Jones uses on her mobile device our Novel Shared Decision-Making Tool that was developed based on patient preferences.

She is very satisfied with this process.



OUR HYPOTHESIS

Our novel **SHARED DECISION-MAKING TOOL**

is more effective than usual care

based on patient-selected outcomes.

Tool Development Process: Design Thinking

- Patient interviews
- Patient-centered design
- Iterative patient testing

- A web-based app that runs on a PC, phone, laptop, or tablet
- English and Spanish

DAYLIGHT: Design Thinking
Blackbird Web Services

Our Tool Starts with a Journey and a Main Video

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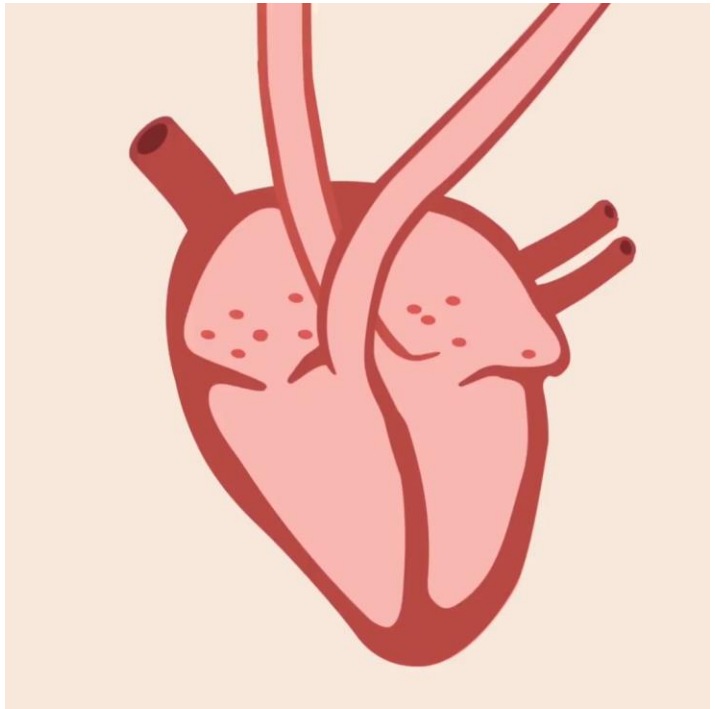
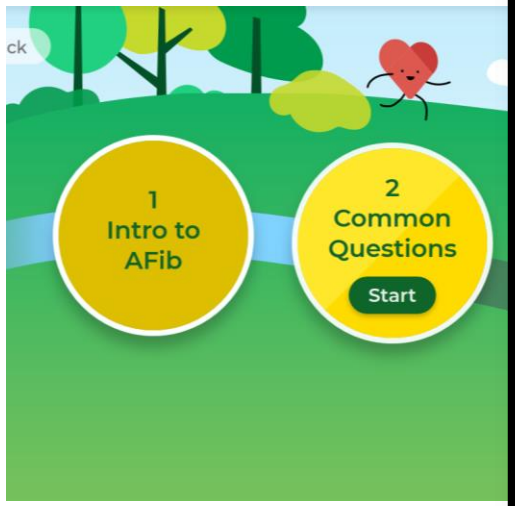
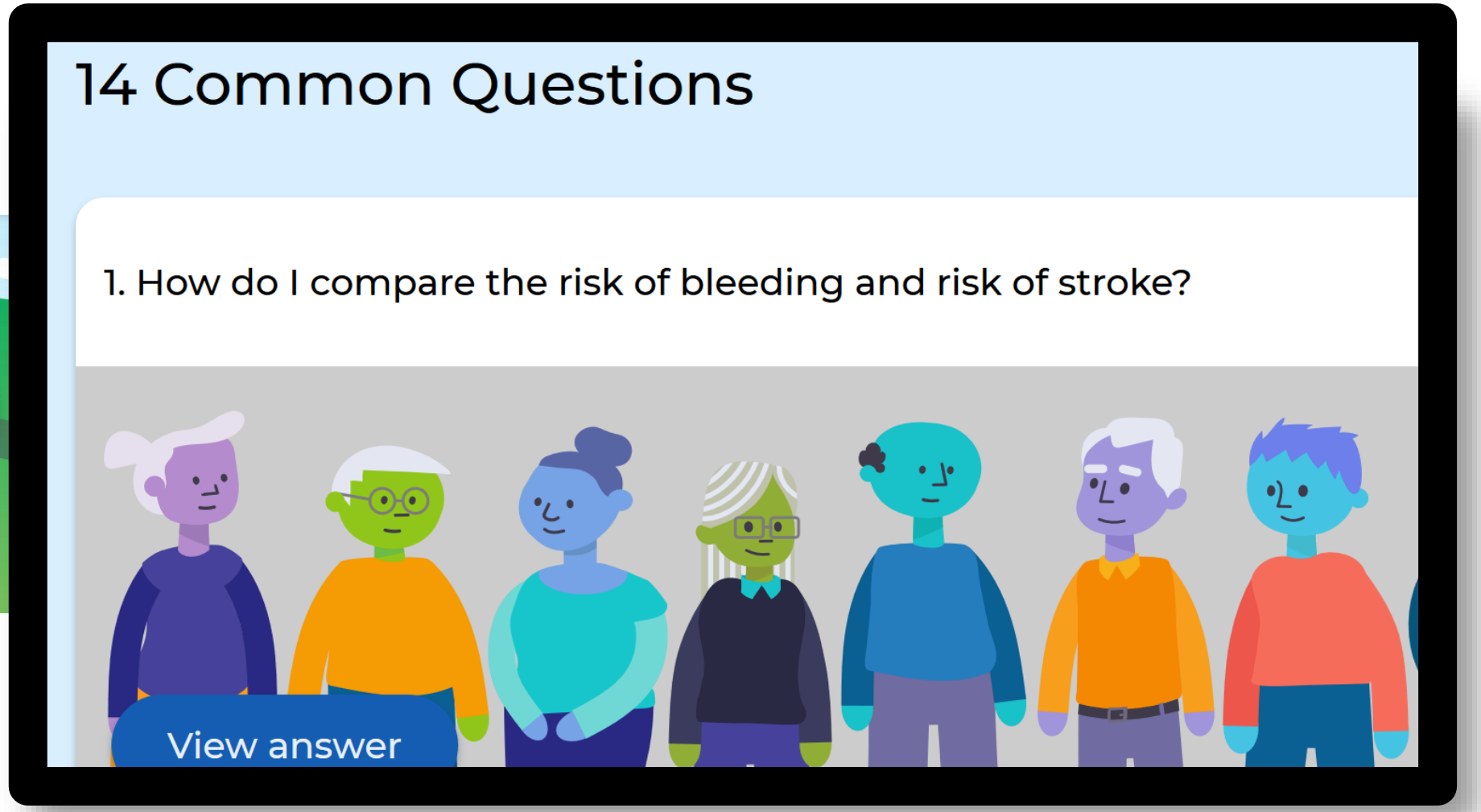
Our Main Video

Uses animation with minimal need for reading

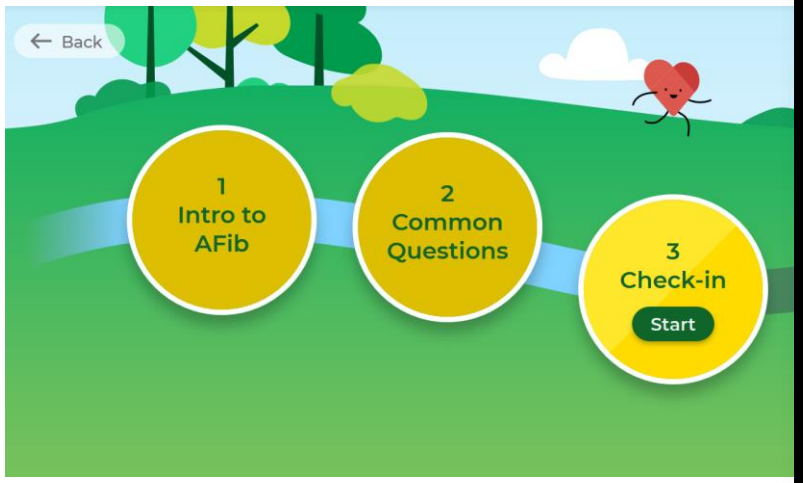


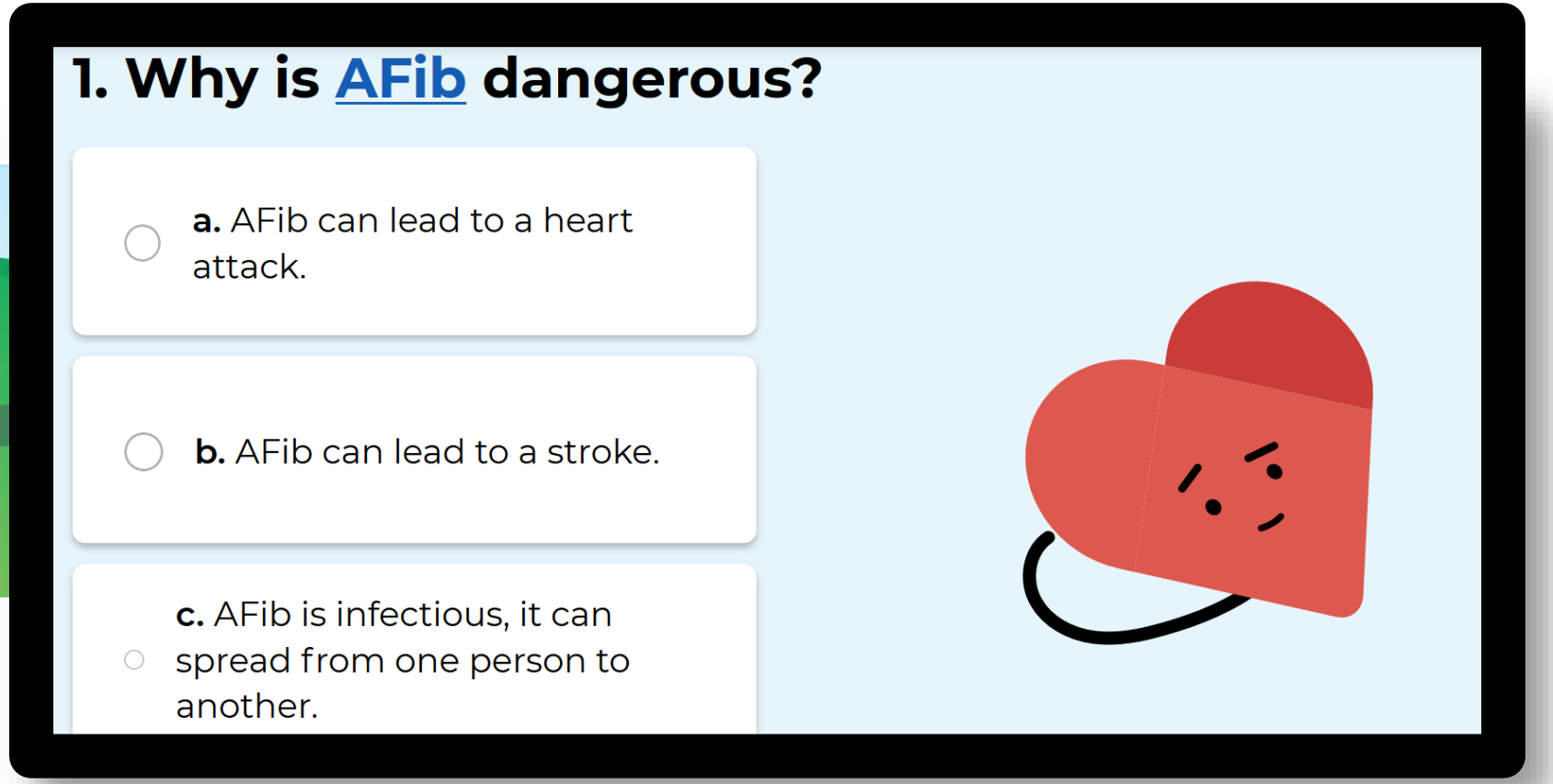
Our Tool Provides Answers to Common Questions



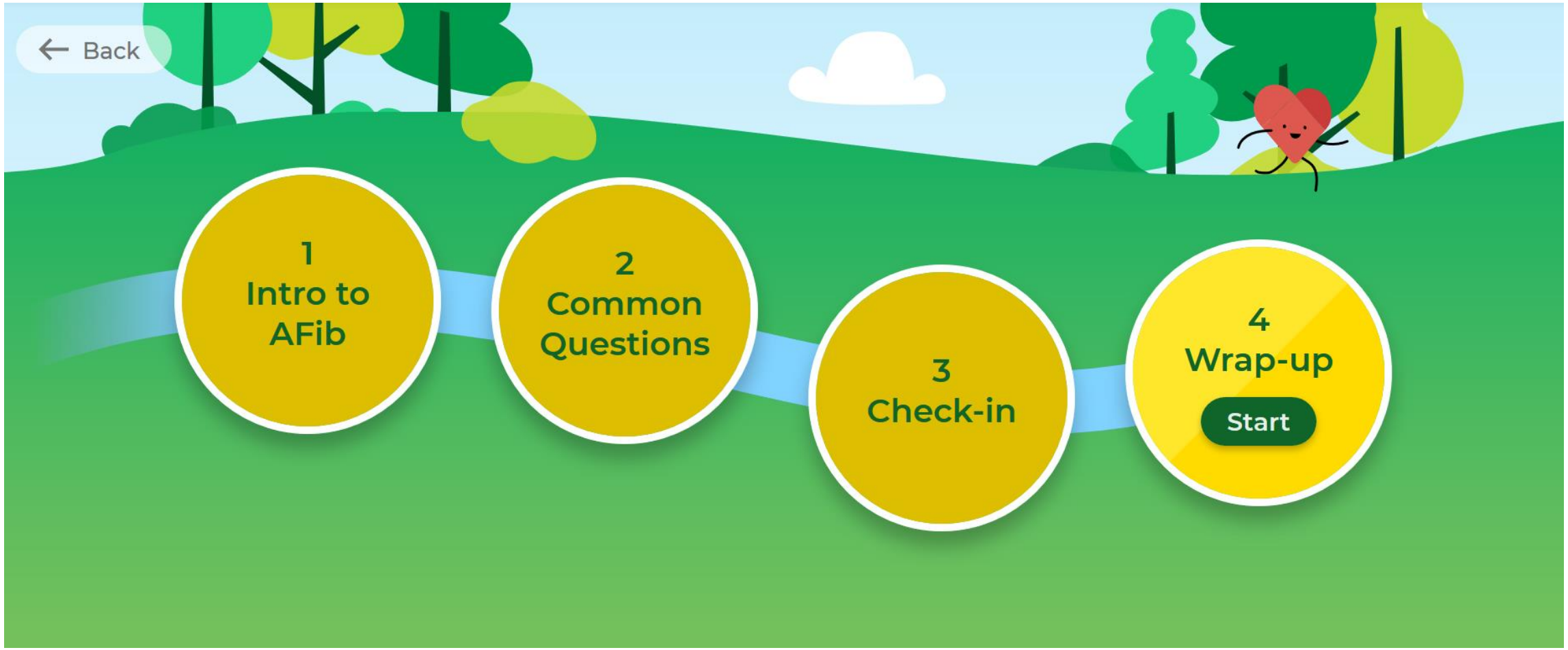


Check-in: A gentle self-assessment

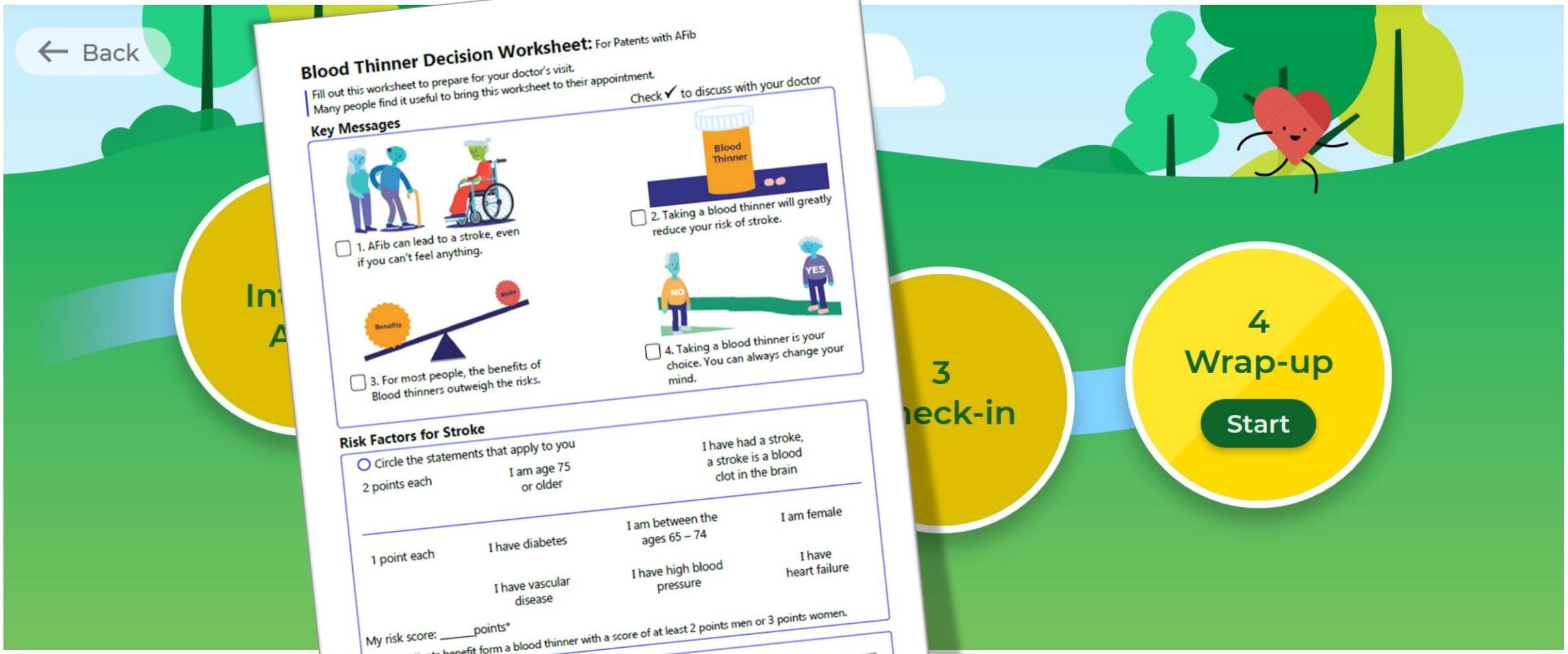




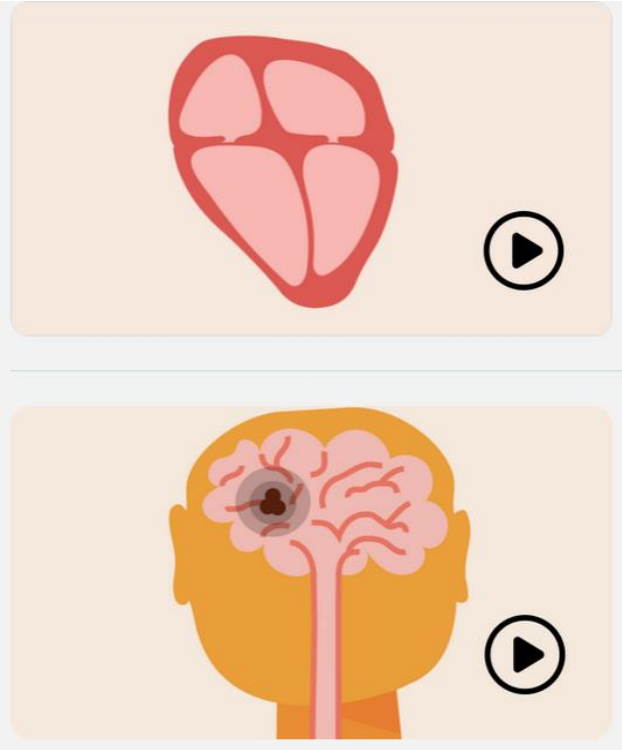
Wrap-Up is the end of the journey



Decision Worksheet:
To be used to discuss questions with the clinician



Clinician Tool provides videos and risk score calculator



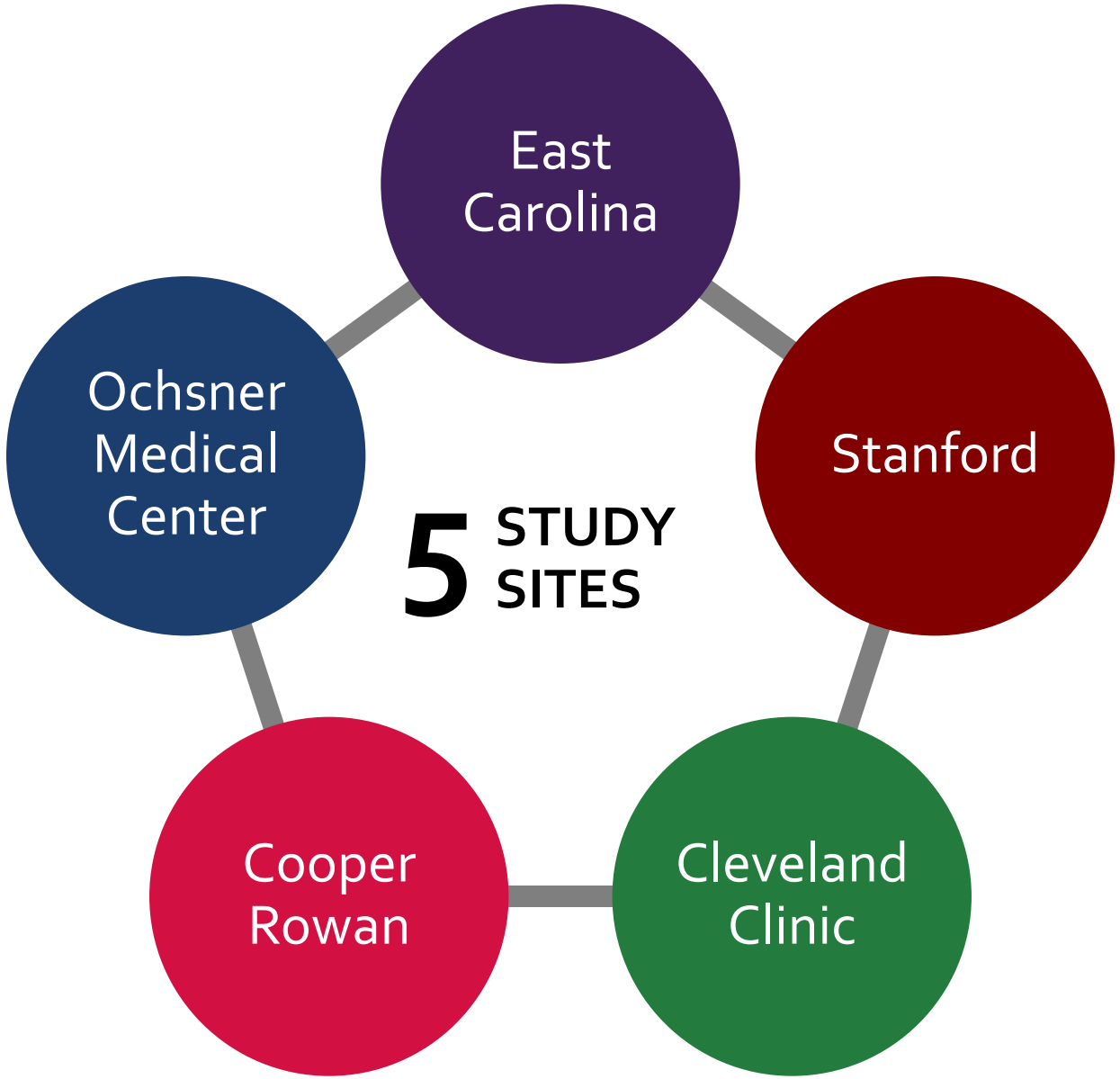
Video:
normal rhythm
vs Afib

Video:
Afib leads
to stroke

CHA_2DS_2-VASc stroke risk factors

Comparative Effectiveness RCT

- 2-Arm Randomized Multi-Site Comparative Effectiveness Trial comparing Novel Shared Decision-Making Tool vs. Usual Care
- 1001 patients at 5 sites
- REGISTRATION: https://www.clinicaltrials.gov
  Unique identifier: clinicaltrials.gov. Identifier: NCT04096781


East Carolina
Ochsner Medical Center
Stanford
5 STUDY SITES
Cooper Rowan
Cleveland Clinic

Inclusion Criteria

- Non-Valvular Atrial Fibrillation
- CHA_2DS_2-VASc ≥ 1 for Men and ≥ 2 for Women
- English or Spanish speakers

Exclusion Criteria

- Moderate to severe mitral stenosis
- Absolute contraindications to anticoagulation
- Left atrial appendage exclusion (by surgery or device placement)
- Any indication for anticoagulation therapy other than atrial fibrillation

Decisional Conflict Score (DCS) at 1 month

Primary Endpoint

- 16-items: Weighted to 0 to 100
- Higher value = more conflict
- Subscores
  - Uncertainty
  - Informed
  - Values Clarity
  - Support
  - Effective Decision

Key Secondary Decision-Making Endpoints

Secondary Endpoints

- Decision Regret Score (DRS) at 1 Month
  Higher = more regret
- Composite of Decisional Conflict Score and Decision Regret Score at 1 Month
  - A weighted average of Mann-Whitney U-statistics for DCS and DRS weighted by fraction selecting each. Higher = more regret or conflict

Lu, Y., et al., *A Composite Endpoint for Treatment Benefit According to Patient Preference.* Statistics in Biopharmaceutical Research, 2022: 1-15.

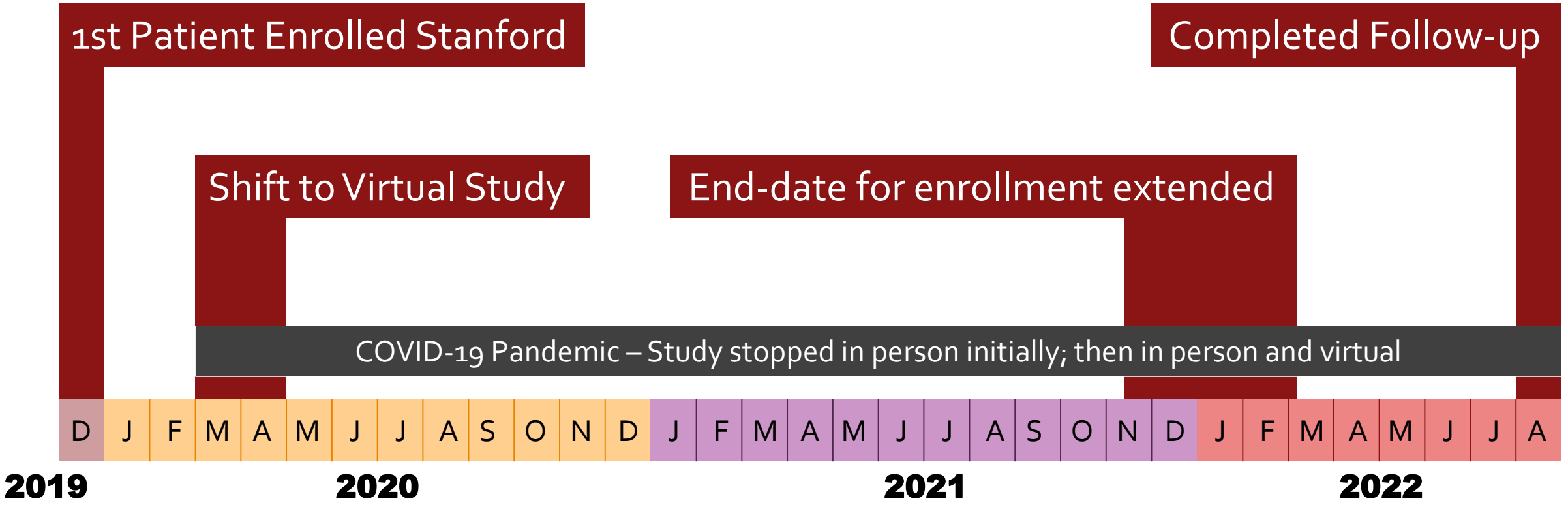
Sample Size Justification

- Sample size was calculated for null hypothesis of no treatment difference under a 2-sided type I error rate of 5%.
- We planed a sample size of 1,000 participants with an anticipated 5% lost to follow-up, leading to a total of 950 evaluable participants.

Endpoint	Effect Size	Power
DCS	31%	99.7%
DRS	20%	84.8%
Composite Endpoint		98.7%

Lu, Y., et al., *A Composite Endpoint for Treatment Benefit According to Patient Preference.* Statistics in Biopharmaceutical Research, 2022: 1-15.

Patient Enrollment: 1001 Patients
START and COVID-19 RESTART

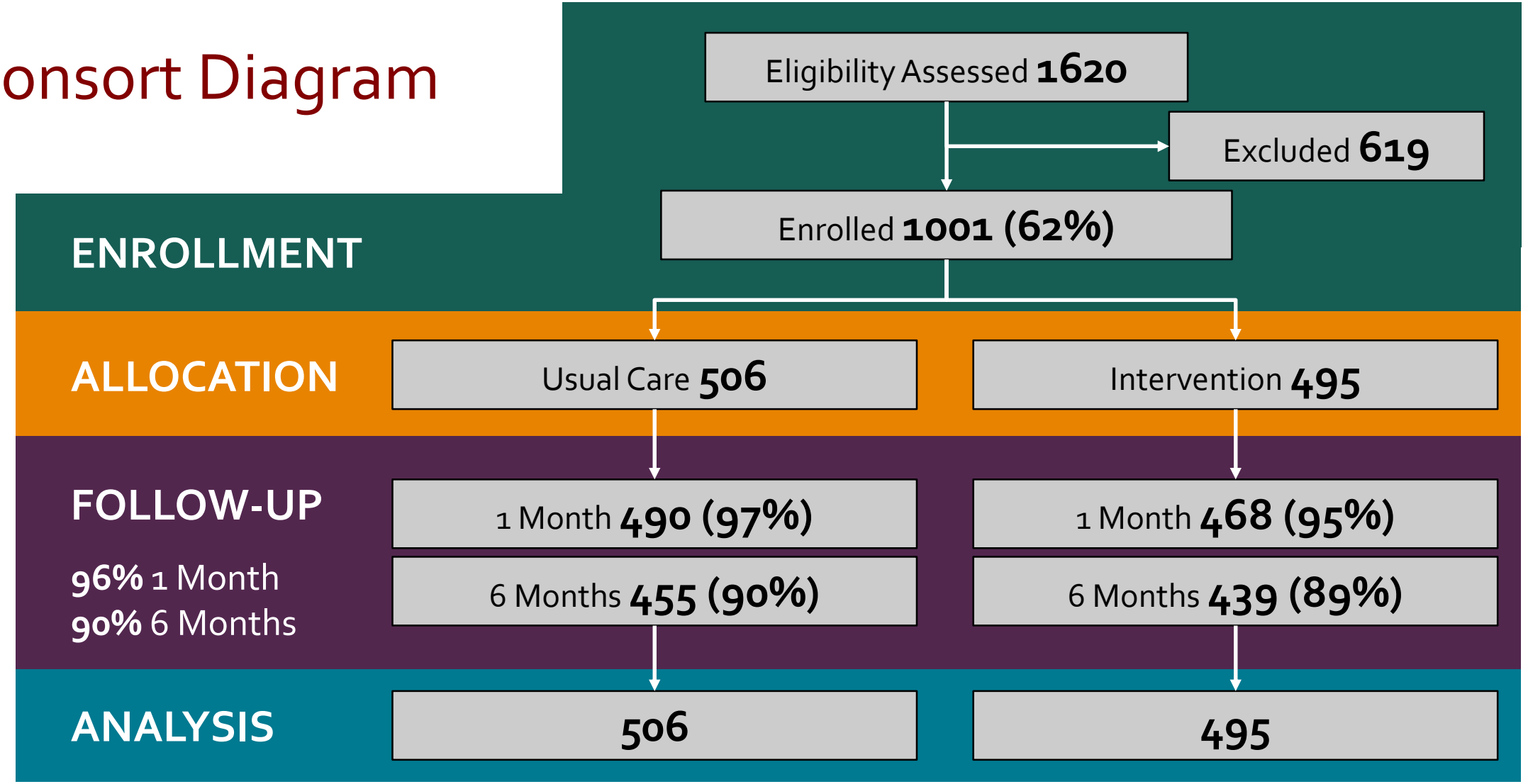


RESULTS

Prepared by Ying Lu, PhD and Amy Lin, MPH
(Data Coordinating Center)

Clinical Coordinating Center Led by
Kenneth W. Mahaffey, MD
Stanford Center for Clinical Research

Consort Diagram



Primary Endpoint: Decisional Conflict at 1 Month

	Usual Care (N=506)	Tool (N=495)	P-value
Decisional Conflict Scale Median	16.4	9.4	0.007

- We observed a clinically and statistically significant decrease in Decisional Conflict at 1 month

Key Secondary Endpoint: Decision Regret at 1 Month

	Usual Care (N=506)	Tool (N=495)	P-value
Decisional Conflict Scale Median	16.4	9.4	0.007
Decision Regret Scale Median	10.0	5.0	0.078#
Composite Endpoint			0.009#
Prep for Decision-Making Median	72.5	82.5	<0.001
AF Knowledge Median	6.0	7.0	<0.001

 # p-values for the two key secondary endpoints were adjusted for multiple testing using Holm-Bonferroni method.

Key Secondary Endpoint: Composite at 1 Month

	Usual Care (N=506)	Tool (N=495)	P-value
Decisional Conflict Scale Median	16.4	9.4	0.007
Decision Regret Scale Median	10.0	5.0	0.078#
Composite Endpoint			0.009#
Prep for Decision-Making Median	72.5	82.5	<0.001
AF Knowledge Median	6.0	7.0	<0.001

 # p-values for the two key secondary endpoints were adjusted for multiple testing using Holm-Bonferroni method.

Other Endpoint: Preparation for Decision Making 1 month

	Usual Care (N=506)	Tool (N=495)	P-value
Decisional Conflict Scale Median	16.4	9.4	0.007
Decision Regret Scale Median	10.0	5.0	0.078#
Composite Endpoint			0.009#
Prep for Decision-Making Median	72.5	82.5	<0.001
AF Knowledge Median	6.0	7.0	<0.001

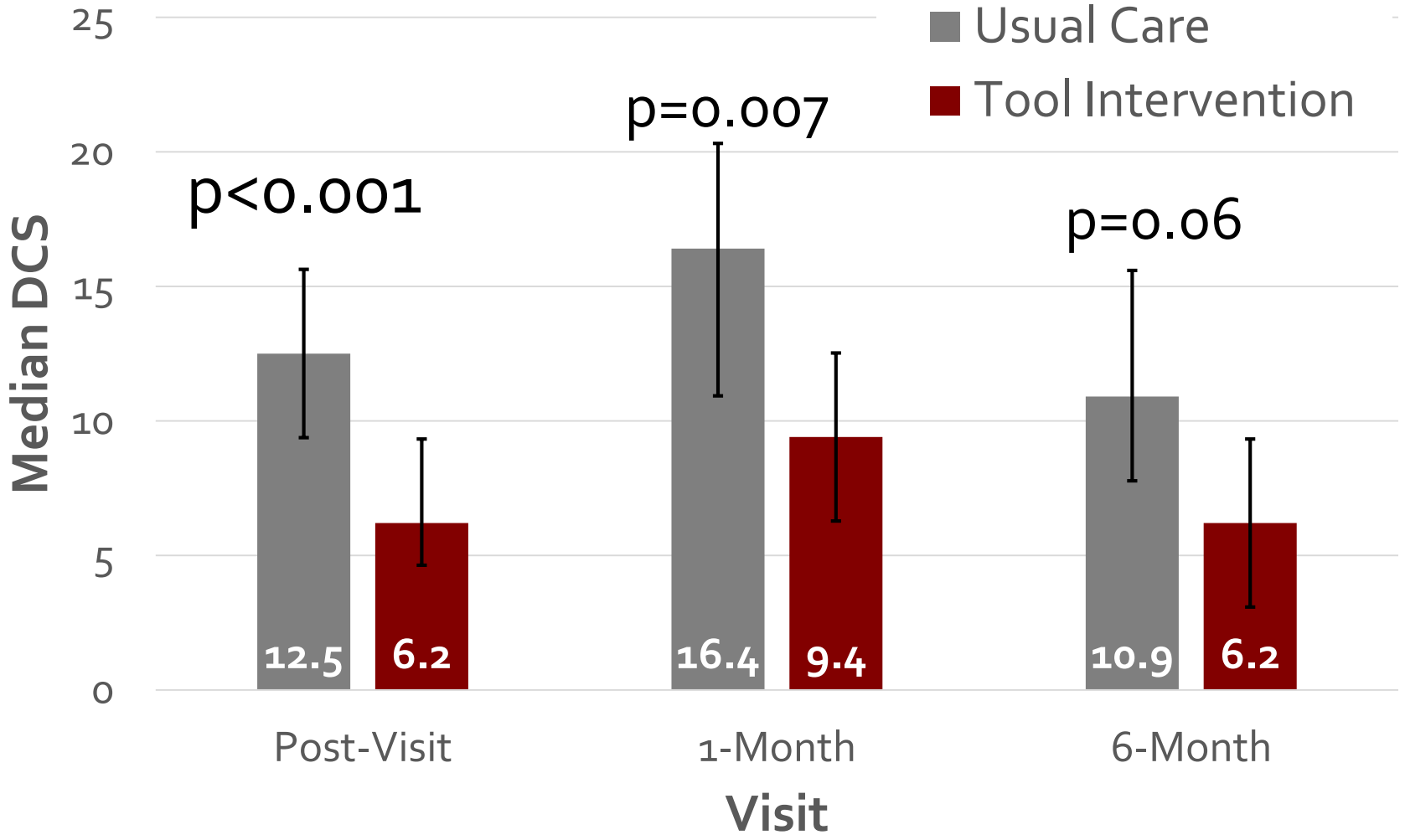
 # p-values for the two key secondary endpoints were adjusted for multiple testing using Holm-Bonferroni method.

Other Endpoint: AF Knowledge at 1 month

	Usual Care (N=506)	Tool (N=495)	P-value
Decisional Conflict Scale Median	16.4	9.4	0.007
Decision Regret Scale Median	10.0	5.0	0.078#
Composite Endpoint			0.009#
Prep for Decision-Making Median	72.5	82.5	<0.001
AF Knowledge Median	6.0	7.0	<0.001

 # p-values for the two key secondary endpoints were adjusted for multiple testing using Holm-Bonferroni method.

Decisional Conflict Score across visits



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Error bars denote 95% confidence interval

Conclusions

- We created and tested a novel Shared Decision-Making Toolkit designed for low health literacy
- At 1 month our shared decision-making intervention resulted in a significant
  - Decrease in Decisional Conflict
  - Improved Preparation for Decision-Making
  - Increased AF Knowledge.

Simultaneous Publication

JAHA
Journal of the American Heart Association

Our novel toolkit is available for widespread use in clinical practice.

afibguide.com

afibguide.com/clinician

Thank You