

LEAP! Rx:

A randomized trial of a pragmatic approach to lifestyle medicine



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Housekeeping

- All participants will be muted upon entry
- Enter **all questions** in the Zoom **Q&A/chat box** and send to Everyone
- Moderator will review questions from chat box and ask them at the end
- Visit impactcollaboratory.org
- Follow us on LinkedIn



Disclosures

- *Amanda Szabo-Reed, PhD, MS-CR and Amber Watts, PhD* have no financial conflicts of interest relevant to this activity.

Background



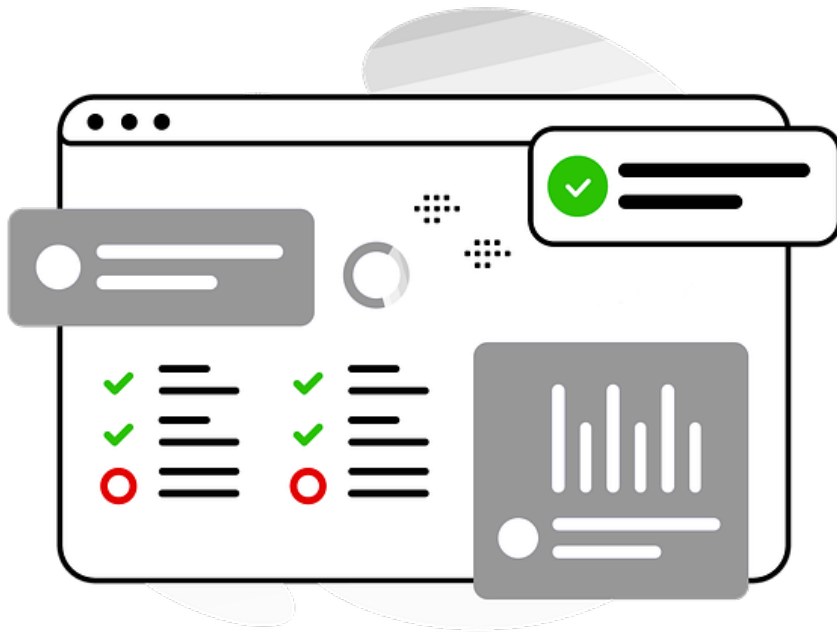
- Exercise is a promising & cost-effective strategy to reduce Alzheimer's disease risk
- CDC recommends 150+ min/week moderate+ intensity aerobic exercise & 2 resistance exercise sessions/week
 - < 15% of adults aged 65+ meet these guidelines
 - Up to 25% are completely sedentary

Translational Barriers

- Laboratory-based studies
 - Limited application to real world settings
 - No meaningful gains in population health
- Few clinician tools support patient adoption & maintenance of exercise
 - Recommendation, little follow up
- Provide clinicians a simple method of referring patients to a program that supports **adoption & maintenance** of exercise for Alzheimer's prevention



Considerations for program design



- Link clinician referrals to community-based fitness resources
- Easily integrate into clinician workflow
- Reduce barriers for patients (motivation, access, support)
- Train local fitness centers to adapt to older participant needs

Study Design



- RCT of a 52-week intervention to support exercise adoption & maintenance
 - Randomized 1:1 LEAP! Rx or standard of care
 - Primary outcome: Cardiorespiratory fitness (VO_2)
 - Secondary outcome: Chronic disease risk factors
 - Tested at 12 and 52 weeks after intervention start
- Cognitively normal older adults (age 65+)
- Two methods of referral to the study
 - Physician referral via electronic health record (EHR)
 - Self-referral via usual channels



Physician Participation

- **54** physicians recruited to refer patients to the program
 - Emails, office visits, presentations about the study, informational pamphlets
 - Six “physician champions” who helped recruit others
- **51.8%** actively referred
 - Internal medicine, endocrinology, family medicine, geriatrics, cardiology, diabetes
 - Feedback Surveys - implementation & scalability

Clinician Referral

- Integrated in existing workflow
- Clinician alerts – patient may be eligible for exercise intervention
- Click a button to indicate interest or decline, sends a “referral order”
- Collaborated with Medical Informatics
 - Identify those potentially eligible from EHR
 - Send physician alert during participant visit
 - Create a referral order to study staff

BestPractice Advisories

Suggestion (1)

✓ Candidate for LEAP! Rx Exercise Program Collapse

Select **INTERESTED** or **DECLINED** below. If interested, a program coordinator will follow up with the patient.

The participating YMCAs are:

1. Parkville: Platte County Community Center South
2. Prairie Village: Paul Henson Family YMCA
3. Blue Springs Family YMCA
4. North Kansas City YMCA,
5. Olathe Family YMCA

Respond to Study Do Not Respond **LEAP! Rx Exercise Program**

☒ Interested ☐ Declined

✓ Accept (1)

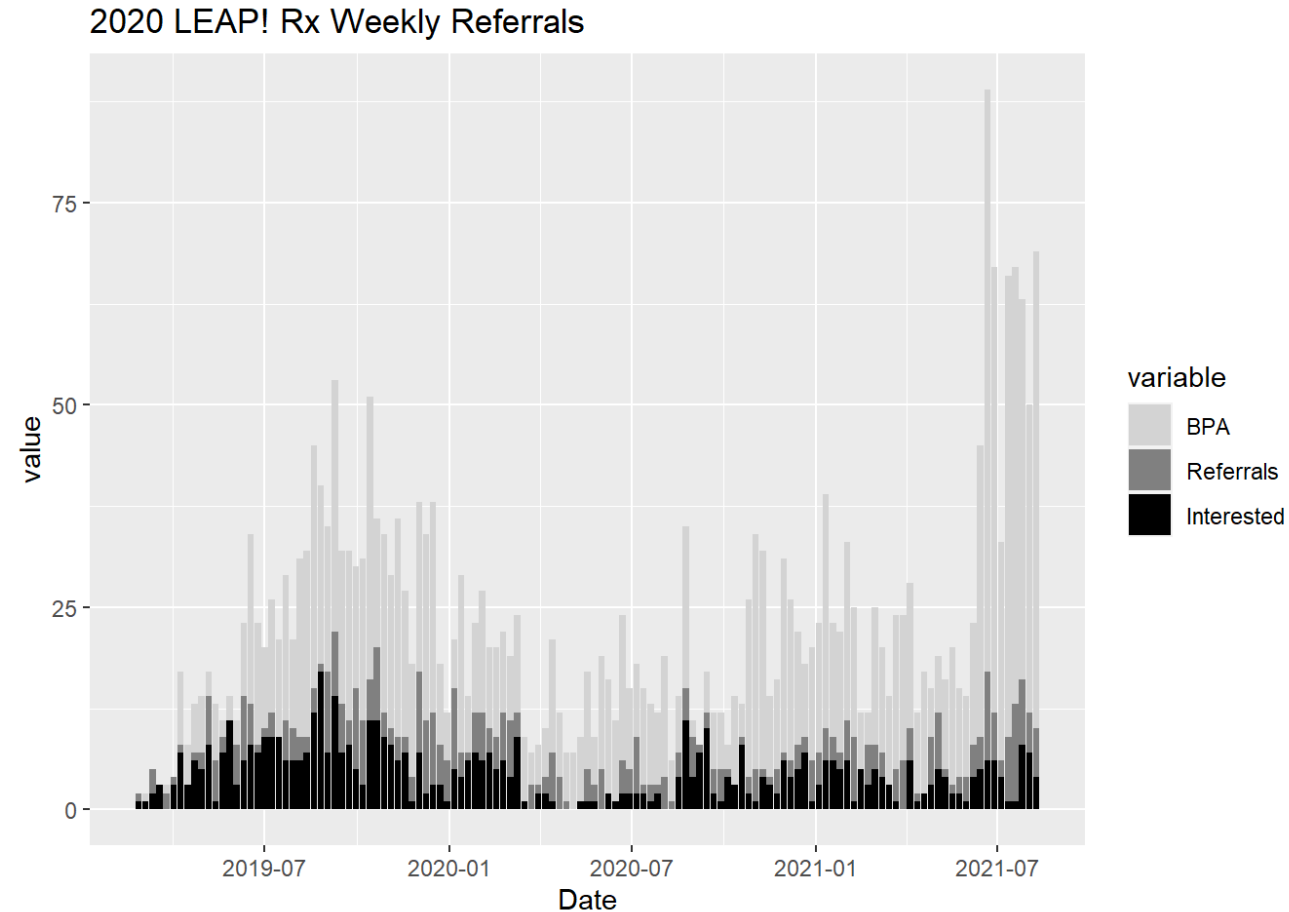
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“Interested” or “Declined” selected:

- Patient linked to study in EHR
- InBasket message to Coordinator pool
- Epic Reporting Workbench report used to manage patient list

Referral Rates

- 3,463 physician referrals vs. 125 self-referrals
- Drops off between
 - eligibility & referrals received
 - referral and interest
- Energy efficient recruitment strategy





Demographic Representation

- Clinical trials often struggle to recruit representative samples
- Physician referral method resulted in significantly more racially and economically diverse sample than self-referral method

Participant Characteristics	Physician Referred (n=118)	Self-Referred (n=101)	Statistical significance
% African American	19.5%	3.0%	$p < .001$
Mean Years of Education	15.6	16.3	$p = .002$
Area Deprivation Index (ADI)	50.3	38.6	$p < .001$

Intervention



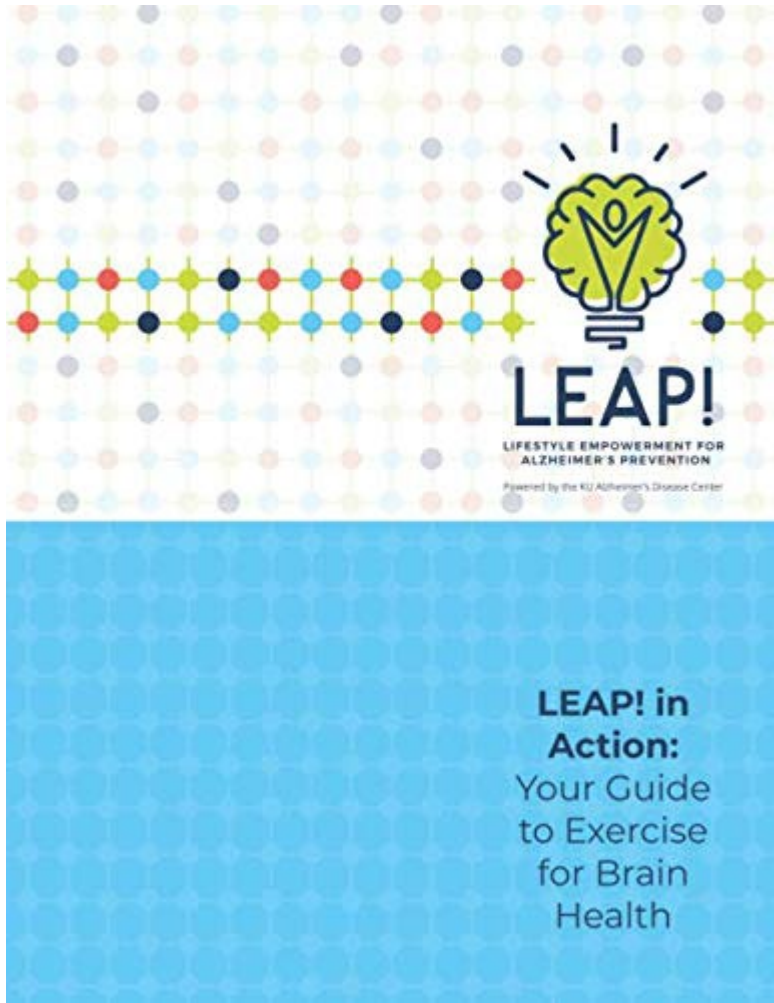
- Gradual increase to reach 150 min/week of moderate to vigorous exercise
 - 12 weeks 1:1 supervised exercise
 - Weeks 1 - 6 twice a week
 - Weeks 7 - 12 once a week
 - 40 weeks intermittent 1:1 supervision
 - Weeks 13 - 52 once a month
 - Gradually wean off trainer support to gain independence
- Intervention Components
 - Regional network of YMCA partners
 - Individual training sessions
 - Optional group fitness classes
 - Optional online Alzheimer's prevention education

Coaching



- Certified Fitness Trainers (e.g., ACSM)
- Trained for our study & exercise adaptations for older adults/physical limitations
 - Set goals and monitor progress
 - Individualized adaptations for safety, comfort
 - Switched to largely online coaching during pandemic
- Standard of Care Control
 - Educational information at baseline
 - Not discouraged from exercise
 - No personal training or join YMCA
 - Waitlist (later access to LEAP Rx program)

Lifestyle Education (online & in person)

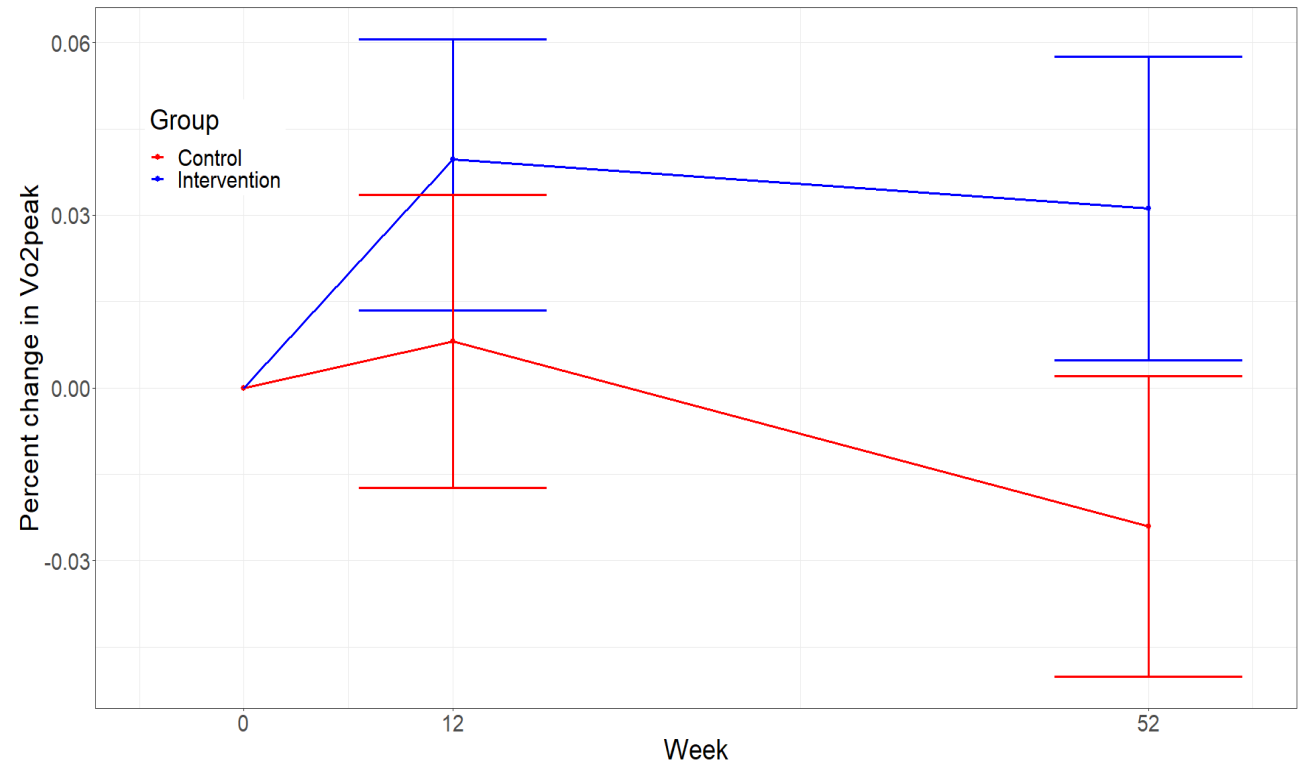


- Throughout the 52 weeks
- Supplemental support for behavioral change & lifestyle integration
- Healthy lifestyle guidebook
- Online lifestyle education classes (monthly)
 - Topics: e.g., nutrition, sleep, stress management
 - Interactive activities and workbook
 - Q & A with a health coach

Change in Cardiorespiratory Fitness

Compared to Control, Intervention group:

- Increased $\text{VO}_{2\text{peak}}$ (wk 12), and maintained increases (wk 52, $p = .005$)
- Those meeting 80%+ of weekly adherence goals had greater fitness improvements ($p < .001$)





Feedback to Clinicians

- Quarterly reports back to clinicians about patient progress
- Promote ongoing dialogue between physicians and patients about exercise habits for longer term maintenance
- Emails automatically generated from database

Dr. Gonzales- Thank you for referring 2 patients to the LEAP! Rx Program. On average, enrolled patients have increased their VO2 peak 1.1 ml/kg/min in the first 12 weeks and lowered their HbA1c 0.01 points.

Your currently enrolled patients:

Initials	Group	Start Date	End Date	Average Weekly Aerobic Exercise (min)	Average Weekly Resistance Training (days)
CB	Immediate Start	11/16/20	11/08/21	127.1	1.9
SF	Immediate Start	12/5/20	11/30/21	119.3	1.7

Discussion

- Physician referral method gives access to
 - Large number of potential participants
 - Some level of pre-screening (safe to exercise)
 - Different types of participants
- Feedback with physicians encourages ongoing support
- Participants had multiple sources of support (trainer, online group, physician)





More about Adherence & Clinician Referral

- Secondary-data analysis exploring differences between clinician-referred and self-referred participants:
 - Recruitment
 - Motivation
 - Adherence
 - Retention

Demographics by Referral Method

Clinician Referred Groups were statistically

- More racially/ethnically diverse
- Lower levels of formal education
- Participation was more disrupted by pandemic

No differences in

- Age
- Sex
- Randomization to intervention vs. control

	Clinician-Referred	Self-Referred	Total Sample
Referral Method (n)	118	101	219
Age, years (Mean, SD)	72.79, 4.83	71.86, 4.82	72.36, 4.84
Sex (n (%))			
Female	98 (83.0%)	80 (79.2%)	178 (81.3%)
Male	20 (17.0%)	21 (20.8%)	41 (18.7%)
Race (n (%))			
White	90 (76.3%)	96 (95.0%)	186 (84.9%)
Historically Underrepresented Groups	28 (23.7%) *	5 (5.0%) *	33 (15.1%)
Ethnicity (n (%))			
Hispanic/Latino	2 (1.7%)	4 (4.0%)	6 (2.7%)
Not Hispanic/Latino	40 (33.9%)	89 (88.1%)	129 (58.9%)
Unknown	76 (64.4%)	8 (7.9%)	84 (38.4%)
Education, years (Mean, SD)	15.75, 2.54	16.24, 2.05	15.97, 2.34
Study Group (n (%))			
Intervention	59 (50.0%)	51 (50.5%)	110 (50.2%)
Control	59 (50.0%)	50 (49.5%)	109 (49.8%)
Enrolled Post COVID (n (%))			
Intervention	27 (34.6%)*	51 (65.4%)*	78 (50.3%)
Control	27 (35.1%)*	50 (64.9%)*	77 (49.7%)



Motivations for Participation

Clinician Referred

- Improving health and contributing to research
- Low value on \$\$ incentives
 - Even lower for clinician referred
- Higher value on clinician opinion of the research ($p < .05$)
- Acknowledgement for participation ($p < .05$) (*correlated with higher adherence)

Self Referred

- Improving health and contributing to research
- Low value on \$\$ incentives



Maintaining Adherence

- Participants entered exercise logs into online database
- Reports auto-flagged participants below 90% adherence
- Study team contacted them to follow up

PT ID	Missing Exercise Log Entry	Average Adherence last 30 days	Adverse Event
77	Week 8	.88	Hip pain
79	Week 16	.50	Carpal tunnel surgery
102	--	.60	Head cold
144	--	.75	Fall



Exercise Adherence by Referral Method

	Clinician Referred (n=59)	Self-Referred (n=51)
Aerobic Exercise Adherence (%)	60.56 (47.06)%*	76.27 (38.12)%
Resistance Exercise Adherence (mean, SD, %)	58.91 (39.59)%*	77.73 (58.07)%
Percentage of Education Classes Attended (mean % (SD))	26.10 (29.20)%	26.47 (31.78)%

Completion of Study by Referral Method

	Physician Referred (n=118)	Self-Referred (n=101)
Completed Intervention (n (%))	78 (66.1%) *	88 (87.1%)
Intervention	39	44
Control	39	44
Withdrew/Terminated Early (n (%))	40 (33.9%) *	13 (12.9%)
Intervention	20	7
Control	20	6

Reasons for Termination or Withdrawal by Referral Method

	Physician Referred (n=40)	Self-Referred (n=13)
Serious Adverse Event (SAE) (n (%))		
Intervention	1 (2.5%)	0 (0.0%)
Control	0 (0.0%)	0 (0.0%)
Loss to Follow-Up (n (%))		
Intervention	8 (20.0%)	2 (15.4%)
Control	4 (10.0%)	1 (7.7%)
COVID-19 Concerns (n (%))		
Intervention	2 (5.0%)	0 (0.0%)
Control	2 (5.0%)	0 (0.0%)
Health Problems (n (%))		
Intervention	5 (12.5%)	2 (15.4%)
Control	1 (2.5%)	2 (15.4%)
Change in Circumstances (n (%))		
Intervention	4 (10.0%)	2 (15.4%)
Control	3 (7.5%)	2 (15.4%)
Problem with Waitlist Group (n (%))		
Intervention	0 (0.0%)	0 (0.0%)
Control	4 (10.0%)	1 (7.7%)
Uncomfortable with Testing Procedures (n (%))		
Intervention	0 (0.0%)	0 (0.0%)
Control	4 (10.0%)	0 (0.0%)
Other (n (%))		
Intervention	0 (0.0%)	1 (7.7%)
Control	2 (5.0%)	0 (0.0%)



Discussion

- This secondary data analysis found that:
 - Self-referred participants had higher rates of adherence than physician-referred participants
 - Physician-referral led to a more racially and ethnically diverse participant sample
- Technology & Adherence
 - Electronic tools allow us to track and monitor adherence in real time



Conclusions & Future Directions

- LEAP! Rx is a first step toward large-scale, real-world programs offering clinicians tools to support healthy brain aging through behavior change relying on existing community-based resources
- Provider electronic referrals are a novel recruitment method that could increase sample representativeness and expand into broader health systems



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Questions?