

Proof of Concept - Ambassador Outreach

Draft Report

Ambassador Outreach for Clinical Trial Recruitment
Project: Yale KET-Trial for Depression in Parkinson's

Dec 2023 through April 2024





Objective:

The Proof of Concept (POC) aimed to evaluate the effectiveness of the “Ambassador” outreach program in enhancing recruitment for the Yale KET-Trial for Depression in Parkinson’s Disease. This initiative involved direct engagement with Parkinson’s support groups and exercise classes by three ambassadors—Daria Lupacchino, Linda Samoncik, and Sophie Elliott—to promote participation in the clinical trial.

Key Findings

Enhanced Engagement:

- The ambassador outreach resulted in a significant increase in participant inquiries and screenings compared to periods without outreach.
- Effective engagement was noted through in-person visits to neurologists’ offices and support groups, as well as personalized outreach.

Successful Strategies:

- Word-of-mouth referrals and presentations at support groups were highly effective in recruiting participants.
- Personalized letters and promotional materials (“swag” bags) contributed to a positive reception and engagement.

Challenges and Areas for Improvement:

- The need for a standardized follow-up process was highlighted, with recommendations for a contact sheet to ensure consistent communication with potential participants.
- There were suggestions to refine communication protocols and enhance digital marketing efforts to improve information dissemination and participant engagement.

Insights and Recommendations:

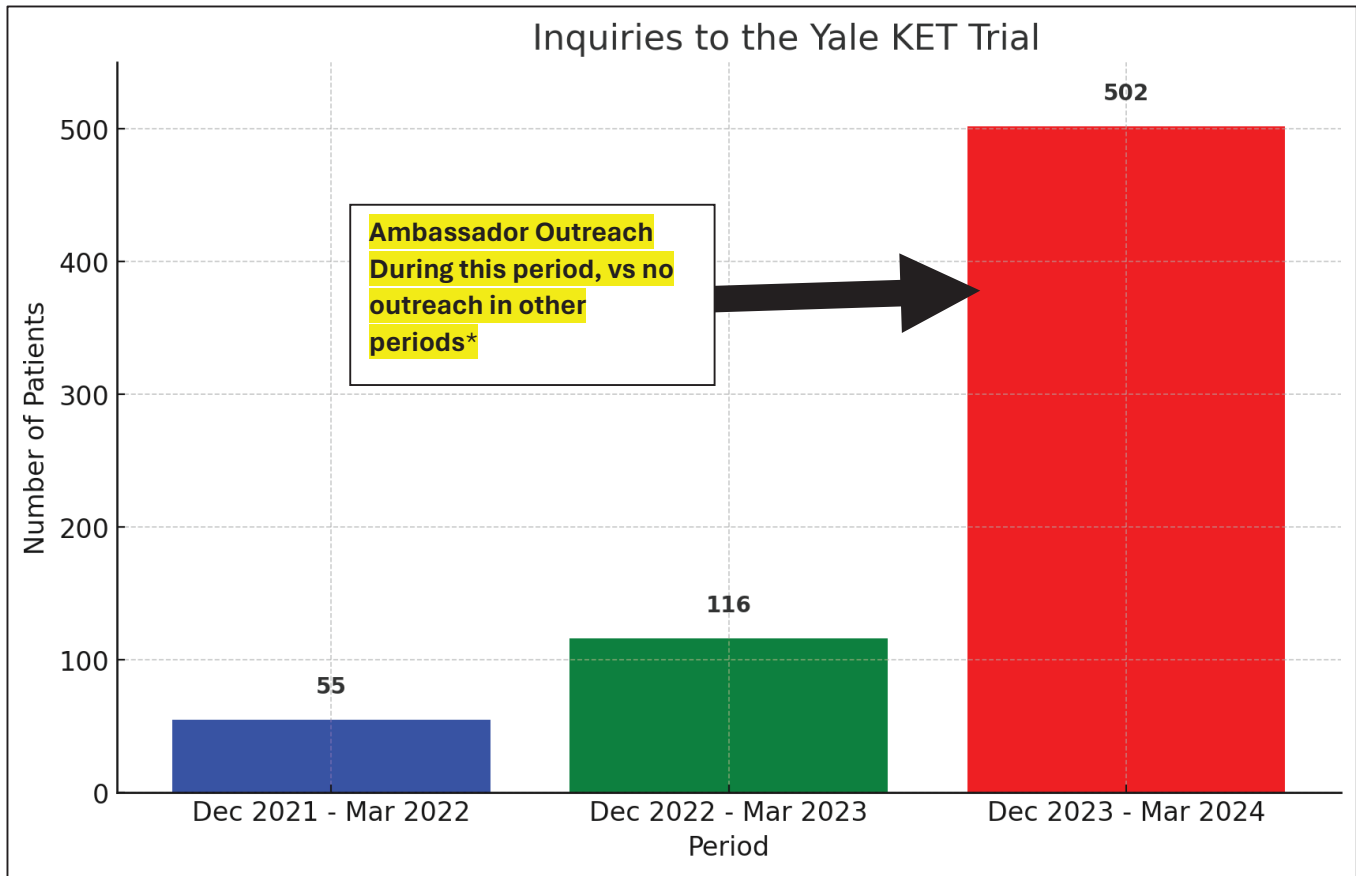
- Establishing a **strategic playbook** is essential for optimizing recruitment efforts, particularly in under-resourced settings.
- Building a network of engaged participants for future research endeavors was identified as a crucial long-term goal.
- Collaborations between stakeholders and continuous feedback loops are vital for refining recruitment strategies and improving outcomes.

Metrics for Success:

- Quantitative data on participant inquiries and enrollments indicated the success of the ambassador outreach compared to previous periods without such initiatives.
- Qualitative feedback from stakeholders emphasized the importance of personalized contact and strategic partnerships in enhancing recruitment efforts.

Conclusion:

The Ambassador Outreach program proved to be a valuable strategy for increasing engagement and participation in the Yale KET-Trial for Depression in Parkinson’s. The success of this POC underscores the potential of personalized, community-based recruitment efforts. Implementing a comprehensive playbook, refining communication strategies, and fostering collaborative networks are recommended to sustain and enhance clinical trial recruitment in the future.



Quick View: What We Were Doing:

Thoroughly evaluating the efficacy of “ambassador” outreach activities as part of the Parkinson’s “Proof of Concept” (POC) Ambassador Program, conducted in Connecticut, recruiting, in this case for the Yale KET Trial.



Daria Lupacchino

The PI’s Point of View:

“we have definitely seen a rise in people getting in touch and also people being brought in for screening. Things have definitely picked up and we attribute this to all the help from Linda and Daria a) targeting neurologist offices; b) spreading the word at support groups; and c) increasing our network of connections”

--Sophie Holmes, PhD, Yale School of Medicine, KET Trial PI



Linda Samoncik



Sophie Holmes, PhD
Yale School of Medicine

Key Outreach/Ambassador Activities

- Personal connections & Networking
- Presentations at support groups and exercise classes
- Distribution of promotional materials and “swag” bags to Neurologists/ MDS
- Personalized letters and visits to neurologist offices
- Regular check-ins with the Yale team to discuss metrics and patient experience

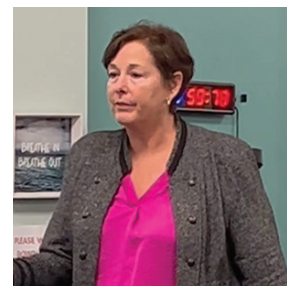
In Detail:



Between December 2023 and April, 2024, these individuals, as Ambassadors, engaged with various Parkinson’s support groups and exercise classes throughout Connecticut, providing presentations, and distributing materials to educate and motivate community members about the importance of participating in clinical trials, and specifically for this POC, the Yale KET Trial for Depression in Parkinson’s.

This summary gathers detailed insights from their experiences, assesses the effectiveness of the strategies employed, and outlines the challenges faced during their engagements. It identifies what worked well and what aspects of the ambassador strategy could be enhanced. Topics include audience engagement, logistical execution, resource allocation, suggestions for improvement, and the overall impact of these efforts on the Yale KET trial.

The Ambassador approach to recruitment for Parkinson’s clinical trials represents a departure from traditional methods by emphasizing personalized outreach and engagement. Unlike the current model, which often relies on generalized communication channels and healthcare professionals for patient identification, the Ambassador program leverages individuals with direct experience or connection to Parkinson’s disease to foster meaningful connections within the community. Through their personal stories, advocacy efforts, and tailored support, Ambassadors serve as relatable and trusted resources, offering invaluable guidance and encouragement to prospective trial participants. This personalized approach not only enhances patient awareness and understanding of available trials but also fosters a supportive network that empowers individuals to make informed decisions about their involvement in research. Ultimately, the Ambassador program offers a unique and impactful pathway for engaging patients in clinical trials, facilitating greater accessibility and participation within the Parkinson’s community.



Daria Lupacchino



Linda Samoncik



Sophie Homes, PhD
Yale School of Medicine

Describe the “Ambassador Program”:



The Ambassador Program drives clinical trial recruitment for Parkinson’s research by using individuals with direct Parkinson’s experience on an in-person, outreach basis. They engage with support groups, exercise classes, and connect with local neurologists and movement disorder specialists. Ambassadors build trust, share personal stories, distribute educational materials, and encourage trial participation. They also bridge the gap between researchers and participants, *supporting future research* and creating a supportive community network.

In this case the ambassadors worked closely with the team at the Yale Ketamine Trial for Depression in Parkinson’s. It was funded by CureNow:PD, and implemented by members of both teams - Yale and CureNow:PD.



Ambassador Linda Samoncik, presents to a support group in Connecticut



Steve DeWitte and Michelle Hespeler - Ambassador “trailblazers”.



1. Yale KET Trial PI, Sophie Holmes, PhD, says:

“I think it (recruitment) remains one of the biggest challenges in research. I think all relevant parties want the same thing but I think a strategic playbook is lacking”



Sophie Holmes, PhD
PI: Yale KET Trial
Yale School of Medicine

2. Statistics:

- Approximately 80% of clinical trials face delays or are closed because of problems with recruitment (1)
- Only 10% of Parkinson’s disease patients participate in clinical trials (2)
- 11% of clinical trial sites fail to enroll **even a single participant**.(3)

3. Gaps between the patient community and the research community:

- **Logistic & Geographic**

Patients often live far from research centers, making participation difficult. The complexity of trial protocols can also deter patients from participating due to the burden of frequent site visits and the need for extensive travel.(4)

- **Technical**

Skill limitations often present challenges to patients using websites and other technical means.(5)

- **Awareness & Education:**

Many Parkinson’s patients and their caregivers are not fully aware of available clinical trials and advanced therapies. (6)

Recruitment efforts for Parkinson’s clinical trials, especially those not sponsored by pharmaceutical companies, often face challenges due to the absence of a standardized approach – a “playbook”, as it is referred to.

These current efforts primarily rely on neurologists for patient identification and referral, as well as a disparate recruiting approach using social media and other, often sub optimally coordinated, tactics, that typically do not include a personalized, in person approach.

The current process may be perceived as fragmented, with activities dispersed across various channels and lacking centralized coordination. This decentralized nature of recruitment efforts can present difficulties in effectively reaching and engaging eligible patients, potentially impacting the enrollment outcomes for non-pharma-sponsored trials.

Footnotes

1. “What Clinical Trial Statistics Tell Us About the State of Research Today.” Antidote, 26 Sept. 2023, www.antidote.me/blog/what-clinical-trial-statistics-tell-us-about-the-state-of-research-today. Accessed May 2023.

2. “Bridging the Gap Between Parkinson’s Patients and Researchers.” Parkinson’s News Today, 2023, parkinsonsnewstoday.com. Accessed May 2023.

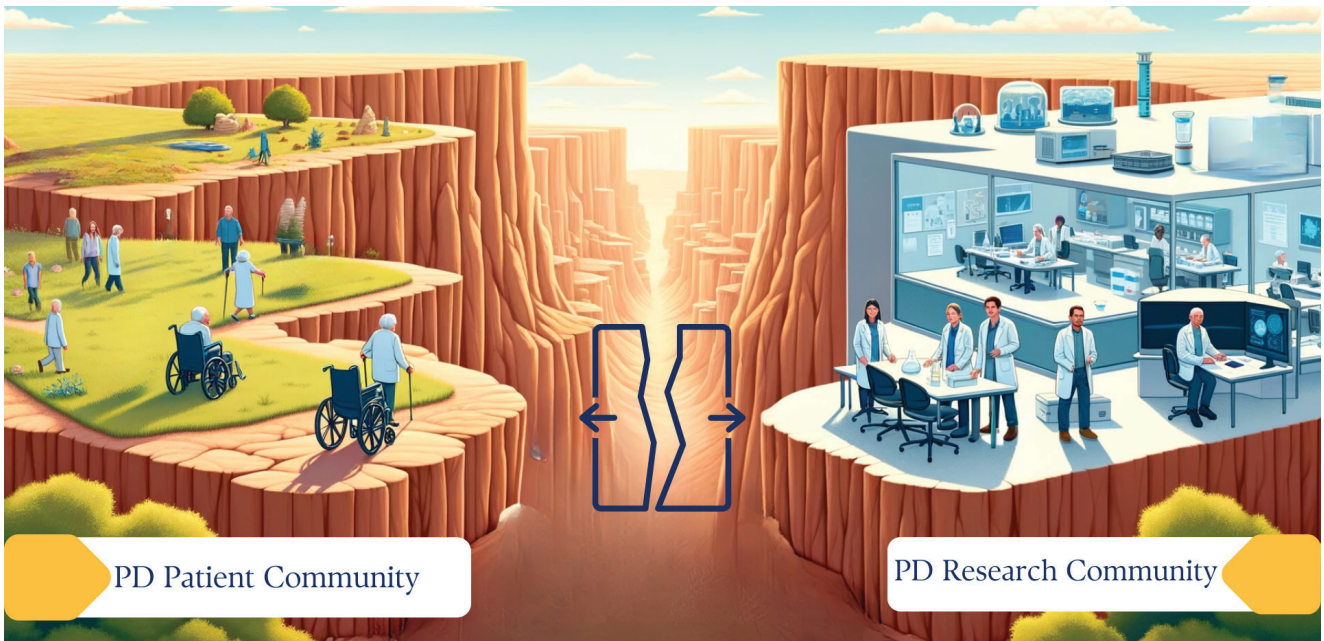
3. “5 Common Clinical Trial Patient Recruitment Challenges and Solutions.” Antidote, www.antidote.me/blog/5-common-clinical-trial-patient-recruitment-challenges-and-solutions. Accessed May 2023.

4. “What Clinical Trial Statistics Tell Us About the State of Research Today.” Antidote, 26 Sept. 2023, www.antidote.me/blog/what-clinical-trial-statistics-tell-us-about-the-state-of-research-today. Accessed May 2023.

5. “5 Common Clinical Trial Patient Recruitment Challenges and Solutions.” Antidote, www.antidote.me/blog/5-common-clinical-trial-patient-recruitment-challenges-and-solutions. Accessed May 2023.

6. “Penn State Health Study Aims to Increase Knowledge and Use of Deep Brain Stimulation for Parkinson’s Disease in Underserved Populations.” Medical Update, Penn State Health, May 2023, medicalupdate.pennstatehealth.org. Accessed May 2023.

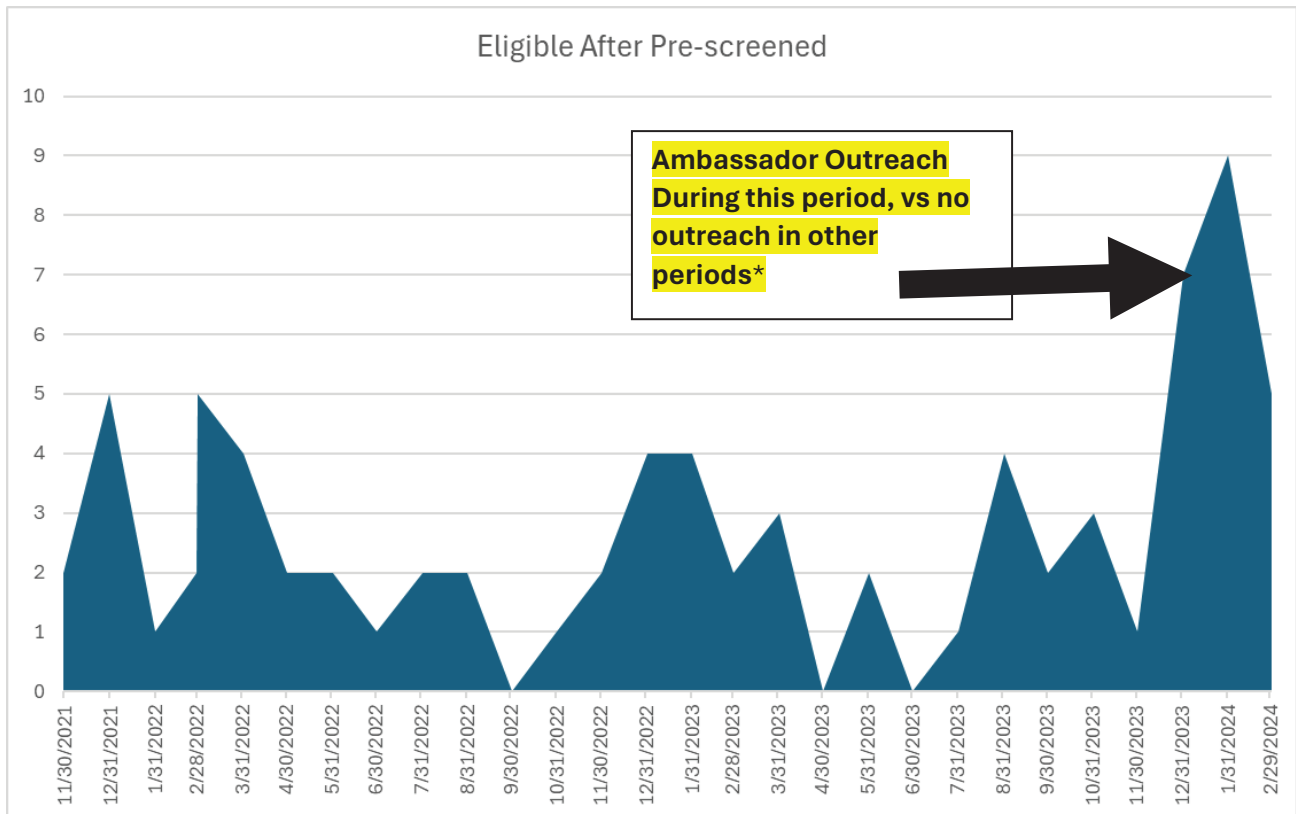
The Gap: Patients/Participants - Researchers



PD Patient Community

PD Research Community

The Numbers-Continued





Ambassador Program Proof of Concept Outreach -Debrief Summary

Period: December 2023 - April 2024

Pages following have detailed comments from participants. Here is the summary:

Significant Increase in Participant Engagement:

- ▶ Ambassador outreach efforts led to a notable rise in participant inquiries and screenings.
- ▶ Initiatives targeting neurologist offices, support groups, and professional networks were particularly effective.

Key Areas for Improvement:

- ▶ **Personalized contact and follow-up** with interested individuals are crucial for sustained engagement.
- ▶ Strategic partnerships and word-of-mouth referrals can enhance recruitment efforts.

Strategic Contributions:

- ▶ A **strategic playbook** is needed to optimize recruitment, driven by funders
- ▶ **Collaboration among stakeholders** is essential for better recruitment outcomes.

Most Effective Tactics:

- ▶ Word-of-mouth referrals and support group presentations are highly effective.
- ▶ Referrals from neurologists build trust and encourage participation.

Recommendations for Improvement:

- ▶ Focus presentations on support groups and fitness facilities **near trial locations**.
- ▶ Improve communication protocols and establish a clear brand identity to maintain participant trust

Key Takeaways (taken from a debrief zoom meet):



Effectiveness Assessment:

- Sophie Holmes, PI, Yale Ketamine Trial, notes a significant rise in participant inquiries and screenings attributed to Ambassador outreach efforts.
- Linda and Daria's initiatives targeting neurologist offices, support groups, and expanding professional networks have notably contributed to increased engagement.

Areas for Improvement:

- Sophie Holmes emphasizes the importance of personalized contact with interested individuals and suggests implementing a contact sheet for effective follow-up communications.
- Sophie Elliott highlights the significance of word-of-mouth referrals and strategic partnerships with platforms like Build Clinical for lead generation.

Strategic Contributions:

- Sophie Holmes underscores the need for a strategic playbook to optimize recruitment efforts, particularly in the context of under-resourced academic and healthcare systems.
- Collaborative efforts between stakeholders, including project funders, coordinators, and PIs, are essential to drive better recruitment outcomes.

Insights from Ambassadors:

Most Effective Tactics:

- Word-of-mouth referrals and support group presentations prove highly valuable for engaging prospective participants.
- Referrals from neurologists play a crucial role in building trust and encouraging patient follow-up.

Attribution of Leads:

- Sophie Elliott outlines methods for tracking lead sources, including improved data collection during participant interactions.
- Efforts to reduce instances of "source unknown" contribute to enhanced data accuracy and informed decision-making.

Importance of Participant Experience:

- Geoff Woolery emphasizes the significance of establishing trust in the recruitment process to foster ongoing participant engagement and positive word-of-mouth.

Building a Network for Future Outreach:

- Karl Hespeler advocates for sustained community engagement beyond individual trials to build a network of engaged participants for future research endeavors.

Recommendations for Improvement:

Targeted Outreach Strategies:

- Linda and Daria propose focusing presentations on support groups and fitness facilities closer to trial locations to improve accessibility and participation rates.
- Personalized follow-up letters accompanying promotional materials can enhance participant engagement and communication.

Optimizing Communication Channels:

- Daria suggests refining communication protocols to ensure timely follow-up emails with accurate information and responses to participant inquiries.
- Geoff Woolery emphasizes the importance of establishing a clear brand identity and reliable communication channels to maintain participant trust.

CureNowPD Presentation Schedule and Update - Yale Ket Trial

Presentation date/time	Support Group/Exercise Group	Support Group POC	Remarks	Audience Total:
Jan 5, 2024 (Fri) 10 am	Beat PD Today - 102 Pitkin St, East Hartford	Michelle Hespeler - 860-918-9594	Kelly, Linda, Daria, Brenda - Presented and gave out informational materials	10
March 7, 2024 (Thurs) 12 pm	Wolcott Rock Steady Boxing, 534 Wolcott Rd, Wolcott, CT	Stephanic Ballesteros; inyourcornerboxing@yahoo.com	Linda, Daria - Presented and gave out promo items and informational materials.	10
March 8, 2024 (Fri) 10:15 am and 10:45 am	Suffield Rock Steady Boxing, 11 High St, Suffield, CT	Donna Calabrese; 860-729-8614; hitsandkicksllc@GMAIL.COM	Linda, Daria - Presented and gave out promo items and informational materials.	16
March 19, 2024 (Tues) 4:50 pm	Deep River/Middlesex County Rock Steady Boxing, 500 Main Street, Unit #10, Deep River CT	Britt Nystrom; 860-301-9291; bnystrom12@outlook.com	Linda, Daria - Presented and gave out promo items and informational materials.	20
March 20, 2024 (Tues) 1 pm	Millford Parkinsons Support Group, 70 Gulf St	Theresa Swan, RN - 203-874-5070	Sophie E. presented and gave out informational materials.	30
March 20, 2024 (Wed) 1:30 pm	Mystic - Masonic Care, 45 Clara Dr	co-facilitators Cathy Gualtieri and her husband Jack Alkon - 860-287-0202; jha211@tvvconnect.net	Linda, Brenda, Daria - Presented and gave out promo items and informational materials.	22
March 23, 2024 (Sat) 10 am	Torrington - Sullivan Senior Center, 88 East Albert St	Sue Pelchat - 860-201-7913; spelchat6@gmail.com	In-person meeting cancelled due to bad weather in Litchfield County. CureNow presented via Zoom. Informational materials provided via email. Promo items will be mailed to Sue Pelchat to give out at their next in-person meeting.	27
March 27, 2024 (Wed) 10:15am	Westport - Senior Center, 21 Imperial Dr	Diane Bosch - dianebosch@yahoo.com; Holly Betts, Assistant Director for Diane; hbetts@westportct.gov; 203-341-5099	Linda, Daria - Presented and gave out promo items and informational materials.	14
April 16, 2024 (Tues) 7 pm	New Canaan - YMCA, 564 South Ave	Lynn Hagerbrant - 203-253-0002; hagerbrant@gmail.com	Dr. Sophie Holmes presented.	20
April 17, 2024 (Wed) 3 pm	New Britain - Hosp for Special Care, 2150 Corbin Ave	Krista Orszulak - 860-827-1958 ext 4071; korszulak@hfsc.org/ Fran Gadd (Linda POC)	Daria - Presented and gave out promo items and informational materials.	10
April 18, 2024 (Thur) 2 pm	Old Saybrook Parkinson's Support Group - 220 Main St, Old Saybrook (@Estuary - use address for the Paperback Café - drive to back parking lot)	Hilary Weissberg - 203-812-0036; hilary.eve@gmail.com	Linda, Daria - Presented and gave out promo items and informational materials.	6
April 23, 2024 (Tues) 1 pm to 4pm	Beat PD Today - 102 Pitkin St, East Hartford	Michelle Hespeler - 860-918-9594	Linda and Kelly - Presented and gave out promo items and informational materials at the PD "Awareness Month" event held at Beat PD Today, East Hartford. Yale's Dr Sophie Holmes presented on Ket trial specifics.	30
May 4, 2024 (Sat) 10 am	Waterbury - The Village at East Farms, 180 Scott Rd	Randi Bellemare, rbellemar@benchmarkquality.com	Brenda and Daria - Presented and gave out promo items and informational materials.	10
June 15, 2024 (Sat) 10 am	Middletown - Grace Lutheran Church, 1055 Randolph Rd.	Sarah Neal - sneal01@comcast.net, (*Sarah oversees program calendar for Martha Gaffe). Martha Gaffe - 860-704-9519		
Total as of 05-08-24				225



“Alone we can do so little. Together we can do so much.”

-Helen Keller



Introduction

This playbook is designed to assist Primary Investigators (PIs) and Study Coordinators in enhancing their clinical trial recruitment efforts. Below, you will find a series of tested strategies and actionable steps that can be followed and checked off upon completion.

Recruitment Strategies

The following strategies have been identified as particularly effective in previous trials and should be considered as part of your recruitment plan.

1. Leveraging Professional Videos

Create and distribute a professional, engaging video explaining the trial's purpose, benefits, and how to participate. Distribute this video through various channels such as social media, email newsletters, and partner organizations.

- Video created and reviewed by the team
- Video distributed to all intended channels

2. Engaging with Neurologists

Develop a concise, informative flyer for neurologists to share with potential candidates during appointments. Include key details such as trial requirements, benefits, and contact information. A QR code, website, and phone number are suggested. Tear off cards and posters are also suggested.

Create a list of key neurologists and have ambassadors deliver “swag” bags with personalized letters from the PI. Include sweets and fun items, also.

- flyer prepared
- swag ordered

3. Utilizing Ambassador Outreach

Recruit and train ambassadors who are well-connected within the Parkinson's community to promote the trial through word-of-mouth, support group presentations, and personal endorsements.

- Ambassadors recruited and trained
- Outreach events scheduled and conducted

4. Digital Marketing

Use targeted digital advertising to reach potential participants. Ensure the ads are placed on platforms frequented by your target audience, and include a call to action that directs them to a pre-screening form.

- Digital ads created
- Pre-screening form responses monitored

Tracking and Follow-Up

Maintain a systematic approach to tracking how participants hear about the trial and follow up with interested individuals. Utilize software or a manual tracking system to log details and monitor progress.

- Tracking system set up
- Regular follow-up calls scheduled with interested participants

Feedback and Adaptation

Regularly collect feedback from participants and stakeholders to refine recruitment strategies. Adjust the approach based on the feedback to improve ongoing and future recruitment efforts.

- Feedback collection mechanism established
- Monthly review meetings scheduled to discuss feedback and make adjustments