Home-based (Site-free) Clinical Trials
Application to Older Adults

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Home-based Trials

AKA ‘Site-free, Virtual, Direct-to-Participant Trials

No clinical sites. No geographic limits on participation.

Home-based Trials: Essential elements

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  - Oral agents by overnight mail
  - Parenteral drugs by home research nurses

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- Patients report AEs to a central site overseen by MD

Advantages for older people

Potential advantages for older people

- Dramatically expands the feasibility to participate in trials
- No travel to sites, parking, hassles
  - Can increase participation by people who have difficulty participating in clinical sites, e.g. those with disabilities
- More diverse enrollees
  - With a larger population to draw from, recruitment can focus on people with comorbidities eg Parkinson’s, racial minorities
- Ideal for vaccine trials
  - Take the trial to those must prone to consequences and death

Potential disadvantages for older people

- Most, not all, have internet access; increasing
- A few older people do not want examinations at home
- Some older people may prefer F2F interactions
  - Some need personal assistance

Examples

REMOTE

Detrol for Overactive Bladder

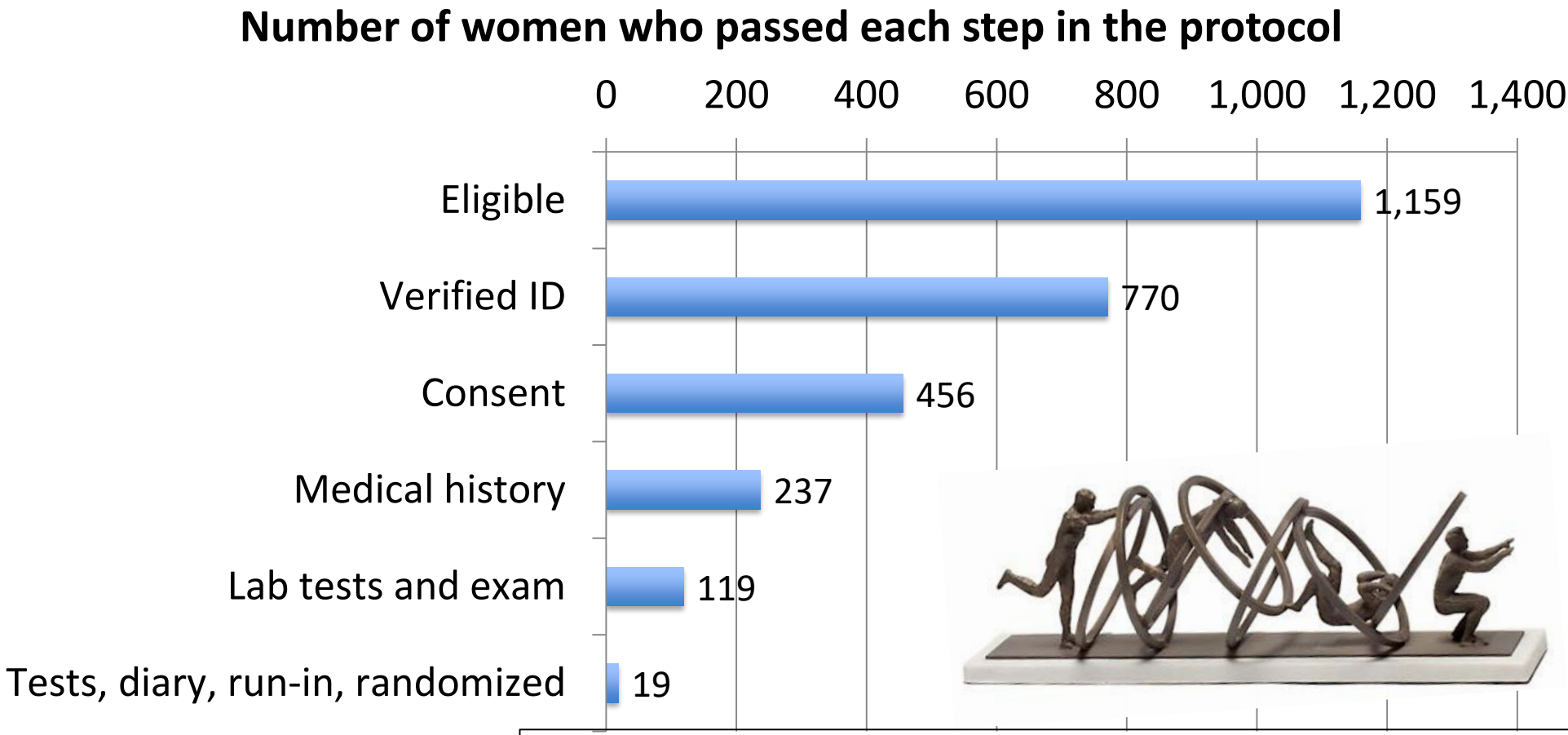
REMOTE funded by Pfizer

- Detrol vs. placebo for overactive bladder
- Done under IND; approved by FDA
- Their goal: Mimic a clinic site-based trial

Complex

- The protocol was very complex
- Many steps
  - >100 screens
  - An average of >90 interactions with a participant to enroll

44-84% of interested and eligible women dropped out at each step



Only 1.6% of eligible and interested older women made it through all of the hoops

Lessons from REMOTE

- FDA is supportive
- The electronic method worked very well
- Complexity killed the trial

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TRIAL OF PARKINSON'S AND ZOLEDRONIC ACID

Preventing Fractures in Parkinson's Disease

- They have a very high risk of fractures
- RCT of zoledronate (ZA) vs. placebo
  - An FDA-approved I.V. drug
  - Increases bone strength
  - Benefits of 1 infusion last more than 2 years
  - Does it reduce fracture risk?

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TRIAL OF PARKINSON'S AND ZOLEDRONIC ACID

- 3,500 participants > age 65
- Requires nationwide recruitment
- Includes PD patients with disabilities and dementia
- No clinic visits. Conducted from patients' homes.
- Simple

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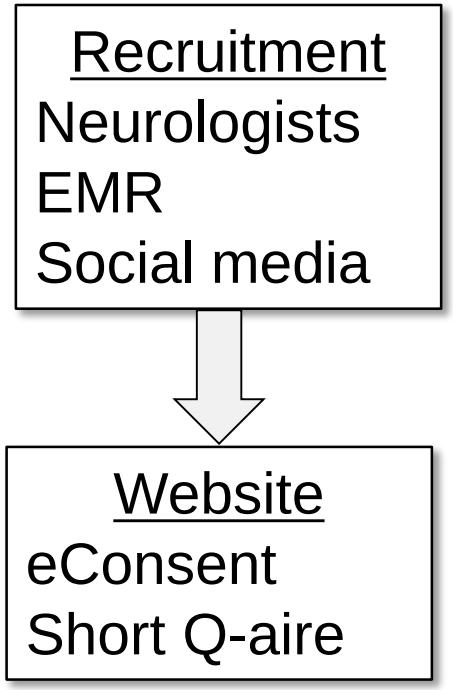
TRIAL OF PARKINSON'S AND ZOLEDRONIC ACID



3 steps

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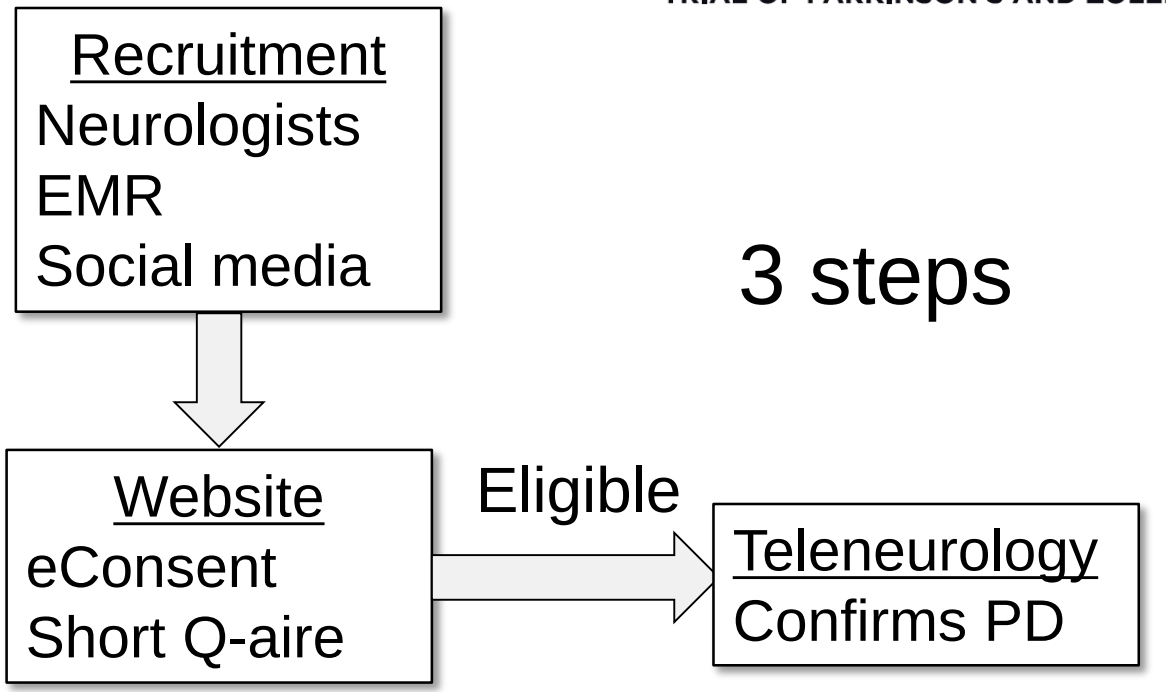

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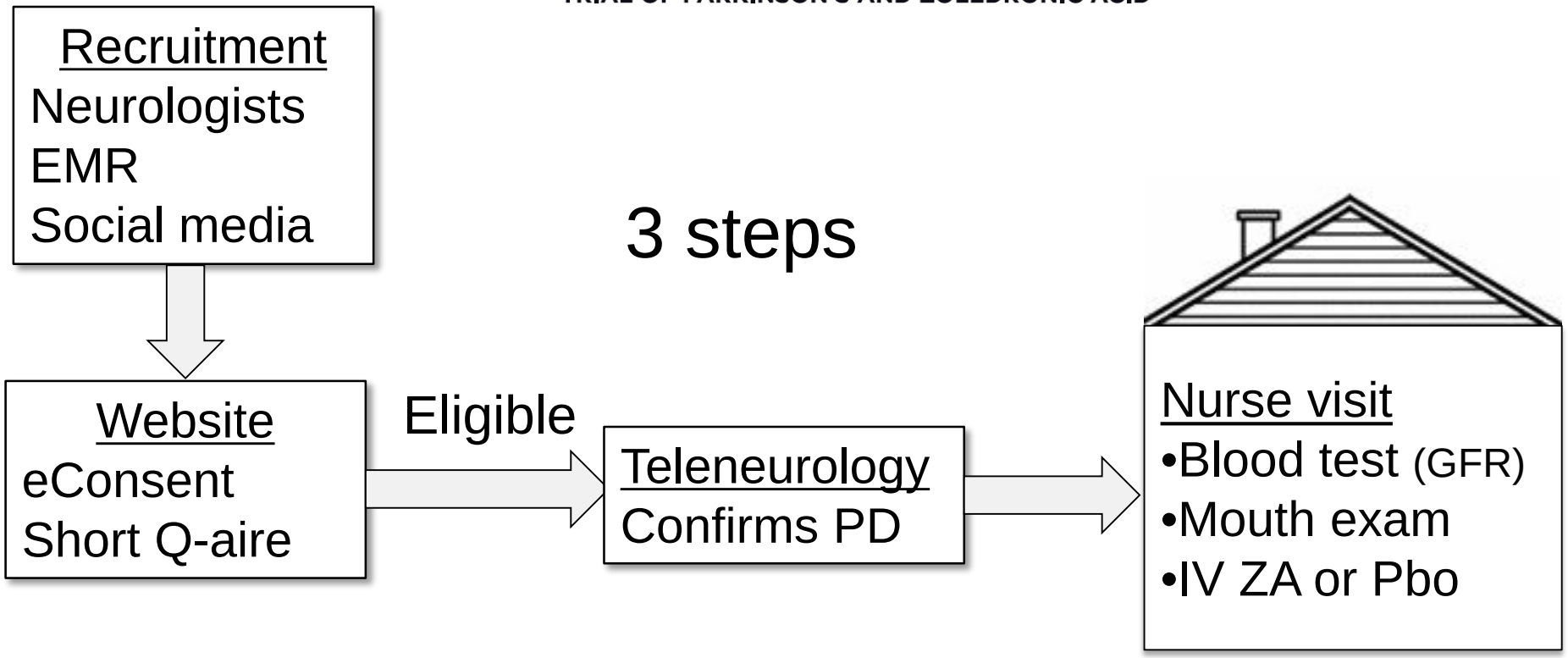

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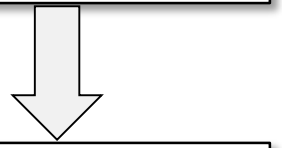
Simpler if referred by a PD neurologist

PD specialist



Website
eConsent
Short Q-aire

Eligible

Nurse visit
- Blood test (GFR)
- Mouth exam
- IV ZA or Pbo

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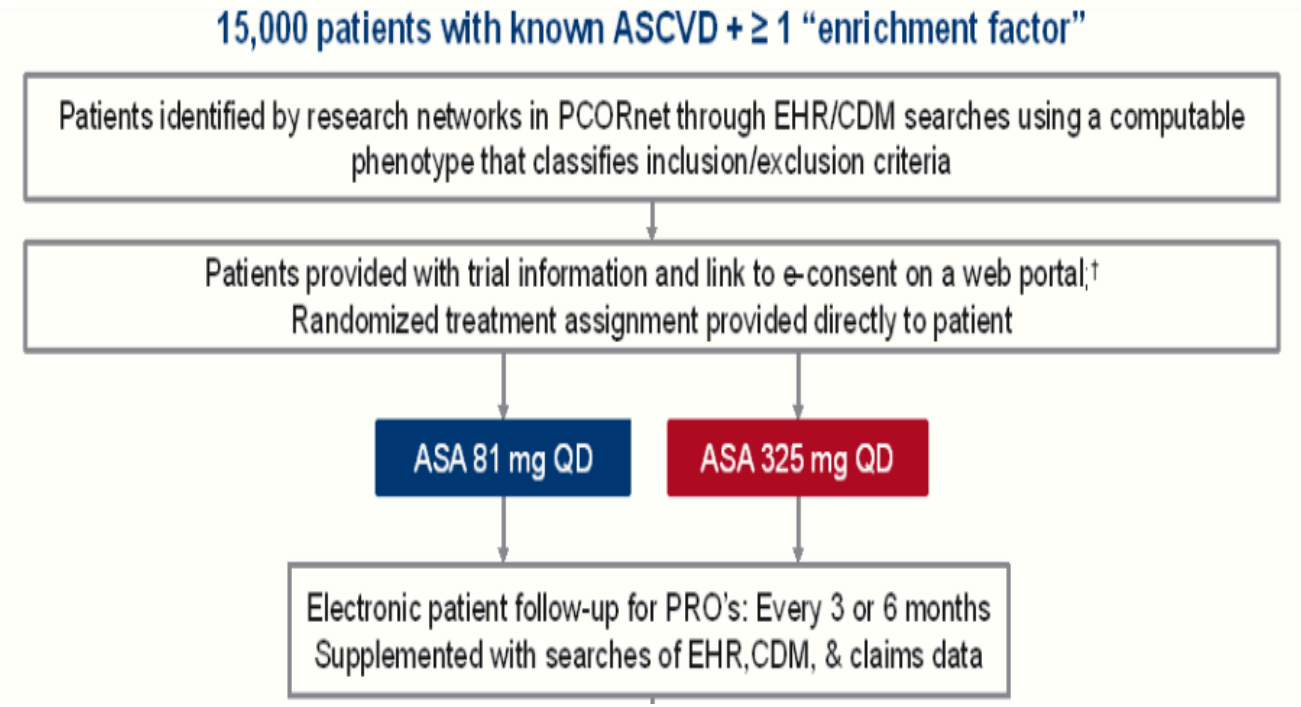
Follow-up call/email q4 months for fracture
AEs: phone line with central MD oversight

Adaptable

The Aspirin Study



15,000 with ASCVD

Identified in EHRs

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Website: information, eConsent

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Randomized, ASA sent to home

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Follow-up by EHR, claims data…

Issues

Limitations

- Many treatment trials must be done in clinical sites
  - They can use elements of home-based trials: “Hybrid trials”
- Compensate for no face-to-face interactions
  - Physicians to refer their patients
  - Nurse home visit
  - One-on-one phone & zoom calls

Summary

- Home-based drug trials are feasible
- They may be particularly useful for older adults
- FDA and IRBs are supportive
- Should be simple


Thank you
Special thanks to Bob Temple