

Health Charities and Participant Engagement

Increasing capacity of disease societies/charities in
promoting recruitment of persons with their target
disease into clinical trials and studies

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Presentation Objectives

1. Discuss consumer and industry challenges to participation in dementia research
2. Consider the role of disease societies via an outline of development and content of *“Clinical Trial and Study Recruitment: A Guide to Get Started”*
3. Review philosophy of Guide using the PARIHS framework
4. Present findings from piloting guide in 8 Alzheimer Society offices



Société Alzheimer Society

Alzheimer Society

CANADA

Clinical Trial and Study Recruitment:
A Guide to Get Started
VERSION 1.0



Clinical trial and study recruitment

A "study" is a term used to refer to any kind of research, whereas a "clinical trial" is a specific type of study that compares one intervention with another.

Studies involve observing the characteristics of groups or populations of persons at one point in time or over time. Clinical trials involve assignment of participants or groups of participants to one or more health-related interventions to evaluate the effects on health outcomes. Interventions in dementia clinical trials and studies may include medications, assistive devices, behavioural treatments, process-of-care changes, preventive care, and others.

Clinical trials and studies can include persons with dementia, persons without dementia, or both.

Clinical trials and studies help:

- Determine if treatments or care practices are safe
- Determine if treatments have any side effects
- Determine if new treatments are better than available standard treatments
- Find out how best to provide care and support
- Find out how people can control their symptoms or improve their quality of life

Clinical trials and studies follow a set of rules, known as a protocol, to ensure they are well designed and as safe as possible, that they measure the right things in the right way, and that results are meaningful. A full protocol should be available to anyone who is considering taking part in a study and wants to see it.

"Study recruitment" refers to the strategies used to identify, approach and connect people with dementia and his or her care partners interested in clinical trials and studies with researchers for possible enrollment in a clinical trial or study.

For more information on clinical trials and studies, please see the Clinical Trial and Study FAQ in the Tools section of this guide.

A good time to start is right now

THE GOOD NEWS

There is an influx of new funding for dementia clinical trials and studies in Canada.¹

THE CHALLENGE OVER THE NEXT 3 YEARS

150,000 people

need to be screened by researchers to yield the approximate

15,000 study volunteers

needed for clinical trials and studies

TO RESPOND TO THE CHALLENGE

The Alzheimer Societies, active in over

150 communities

across Canada, are poised to

connect researchers with potential study volunteers.

1) From: Brain Canada, Weisk Foundation, Canadian Consortium on Neurodegeneration and Aging (CCNA), Ottawa Brainworks, Canadian Longitudinal Study on Aging (CLS), in addition to regular funding from the Alzheimer Society Research Program (ASRP), pharmaceutical companies, and the Canadian Institutes of Health Research.

STEP 1: KNOW WHAT YOU ARE AIMING FOR

INSTRUCTIONS

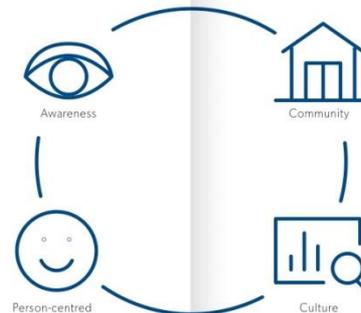
Review the principles below to understand study volunteer recruitment concepts. The principles represent the spectrum of activities that a Society should aim for. Use the Getting Started! Work Sheets in the Tools section of this guide to consider what you are aiming for and start the conversation about the recruitment principles.

Awareness

Clinical trial and study recruitment begins with awareness on two levels: awareness of the need for study volunteers on the part of the Society staff and awareness of study volunteer opportunities for the person with dementia and care partners. Societies interact with persons with dementia and care partners who are actively seeking opportunities to participate in clinical trials and studies as well as those who are not yet aware of the opportunities or what is involved. By working with researchers and raising staff awareness, Alzheimer Societies can connect persons with dementia and their care partners with information about clinical trial and study opportunities in their community.

Person-centred

Clinical trials and studies recruitment should be person-centred: that is, informed by the values and needs of the person. Alzheimer Societies can help researchers to better communicate with persons with dementia and his or her care partners about what is involved in participating in clinical trials and studies and proactively address fears or barriers. Alzheimer Societies can also embed discussions about participation into existing service delivery and support the person and care partners to make informed decisions about participation.



Community

Clinical trials and studies recruitment is a community endeavour. The researcher is responsible for recruitment; however, it takes a community to successfully recruit. By working with researchers, Alzheimer Societies can help ensure research organizations (e.g. hospitals, universities) and researchers connect with community leaders to involve underrepresented, vulnerable, or underserved populations.

Culture

Clinical trials and studies recruitment in Societies is only possible with a positive research culture. A Society that collectively understands the value of participation for the person, his or her caregivers and society can help advance participation in clinical trials and studies in dementia care. Alzheimer Societies can create policies and processes to strengthen working relationships with researchers and help individuals benefit from participation while managing risk. Societies also can identify the roles and responsibilities of staff to be involved in clinical trial and study recruitment and enable a coordinated team effort.

Why clinical trial and study recruitment is important

IT'S GOOD FOR THE PERSON AND CARE PARTNERS. Clinical trials can provide the opportunity to access new, potentially promising treatment options before they become widely available. Studies can help persons with dementia and care partners try out strategies or supports that may improve their quality of life. Participation in clinical trials and studies can also have health and social benefits.

IT'S GOOD FOR THE WORLD. Clinical trials and studies can have a profound impact on preventing, living with and caring for the Alzheimer Society vision and mission of a world without Alzheimer's Disease. Societies advocate strongly for research funding and raise funds for clinical trials and studies funded directly through the Alzheimer Society Research Program. There is a lot of work to be done to advance knowledge around the cause, care and cure strategies for persons with dementia and care partners.

YOU CAN HELP. Researchers are looking for study volunteers to participate in different ways - from participating in a drug trial to completing a survey. As key members of the dementia community, the Alzheimer Societies are well positioned to:

- Bring persons with dementia, care partners, and researchers together
- Help clinical trial and study recruitment efforts to be person-centred
- Support informed choice to participate in clinical trials and studies
- Communicate clinical trial and study opportunities to the person with dementia and care partners
- Help share clinical trial and study results
- Help share the experiences of those who have participated in a clinical trial and study

So why are we talking about study volunteer recruitment? Because it's good for the person with dementia, it's good for care partners, it's good for the world and you can help.

Participation in clinical trials and studies has the potential to positively impact everyone's future understanding and approach to Alzheimer Disease.

A Good Time to Start is Right Now

- **The good news:** There is an influx of funding for dementia clinical trials and studies in Canada*
- **The challenge over the next three years:** 150,000 people need to be screened by researchers to yield the approximate 15,000 study volunteers needed for clinical trials and studies
- **To respond to the challenge:** The Alzheimer Societies, active in over 150 communities across Canada, are poised to connect researchers with potential study volunteers

*Brain Canada, Weston Brain Institute, Ontario Brain Institute, Alzheimer's Drug Discovery Foundation, AGE-WELL, Baycrest, Canadian Institutes of Health Research including the Canadian Consortium on Neurodegeneration in Aging and the Canadian Longitudinal Study on Aging. Source: Clinical Trial and Study Recruitment: A Guide to Get Started. Version 1.0. Alzheimer Society Canada, Toronto, September, 2014.



Consumer Challenges to Participation in Dementia Research

- Lack of awareness
- Physician challenges
- Study partner requirement
- Trial design
- Cultural and linguistic differences
- Socioeconomic status and educational factors
- Coexisting conditions

Source: "Participation in Dementia Trials and Studies: Challenges and Recommendations Paper Prepared for Global Action against Action against Dementia by Alzheimer's Disease International Member Charities" Alzheimer's Disease International, 2014



Industry Challenges to Participation in Dementia Research

- Multiple regulatory processes
- Variation in assessment tools and measures
- Uncertain return on investment



What Countries Can Do to Address the Challenges to Dementia Research

- Increase funding for dementia research
- Increase public awareness of Alzheimer's disease and other dementias
- Increase awareness of dementia research
- Incorporate dementia research into the care continuum
- **Improve access to clinical trials and other studies**



Clinical Trial and Study Recruitment: A Guide to Get Started

- Objective
 - Improve 150 Society offices' capacity to recruit volunteers to clinical trials and studies
- Phases
 - Scoping literature review, environmental scan of Society offices recruitment philosophies & practices, draft the Guide,
 - Guide piloted in 8 offices, Guide revised,
 - Guide offered to federation of Societies in Canada



Clinical Trial and Study Recruitment: A Guide to Get Started

- Content (Version 1.0):
 - Clinical trial and study recruitment
 - Why clinical trial and study recruitment is important
 - How this guide came to be
 - What this guide is for
 - Steps to get you started
 - Know what you aiming for (recruitment principles)
 - See how it can be done (scenarios)
 - Determine where you want to go (context analysis)
 - Plan how you will get there (planning)
 - Tools to support you along the way



The PARIHS Framework

- Promoting Action on Research Implementation in Health Services: a function of interplay of three core elements
 1. Level and nature of *evidence*
 2. *Context* or environment into which evidence is to be used
 3. Method or way in which the process is *facilitated*
- That is, the *evidence* alone is not enough to change behavior of individuals and/or organizations



“Evidence” in the PARIHS Framework

- Research evidence may be presented as:
 - unsystematic, anecdotal, and descriptive, or
 - as rigorous systematic (quantitative or qualitative) evaluation
- Professional consensus may be
 - widely divided or
 - high levels of consensus may exist, and
- Patients' opinions may range
 - from being completely overlooked to
 - process of systematic feedback and input into decision making



Use of “Evidence” in the Clinical Trial and Study Recruitment Guide

- Scoping literature review, environmental scan of Society offices recruitment philosophies and practices
- Evidence showed Society capacity to recruit volunteers related to “Context” and “Facilitation” issues in offices across Canada
- Within Alzheimer Society offices across Canada many potential opportunities for recruitment of volunteers into clinical trials and studies
- Uneven recruitment practices and support of researchers in Society offices across Canada



“Context” in the PARIHS Framework

- Context implies understanding of forces at work which give physical environment a character and a feel.
- Context can be subdivided into three core elements:
 - understanding of prevailing culture
 - nature of human relationships as summarized through leadership roles
 - organization's approach to routine monitoring of systems and services...that is, measurement



Use of “Context” in the Clinical Trial and Study Recruitment Guide

- Need for organizational change within 150 Society offices to increase recruitment of volunteers
- Society offices across Canada are diverse, dynamic → broad spectrum of organizational behaviours in recruitment of volunteers
- Structures, processes and procedures required in Society offices to sustain their recruitment of volunteers – cannot be dependent on one champion within office who may leave
- Offices work within federation of Societies and therefore Guide created by Alzheimer Society of Canada cannot be prescriptive
- Guide minimizes need for expert (in-person) facilitation



“Facilitation” in the PARIHS Framework

- Facilitation is a technique by which one person makes things easier for others.
- The term describes the type of support required to help people change their
 - attitudes,
 - habits,
 - skills,
 - ways of thinking, and
 - ways of working.
- Facilitation strategies driven by evidence and context



Use of “Facilitation” in the Clinical Trial and Study Recruitment Guide

- Guide promotes
 - Problem-based (scenarios/cases) learning
 - Small group learning
 - Self-directed learning
- Use of Guide is facilitation strategy to promote increased capacity of Society offices to recruit volunteers
- Guide helps Society offices understand their role in recruitment of volunteers and plan for incremental change



Use of “Facilitation” in the Clinical Trial and Study Recruitment Guide

- Guide aims to inform, encourage dialogue among staff, and enable office personnel to learn and own concepts
- Guide helps users work through a process of problem solving, critical appraisal, critical reflection and active steps that all contribute to active planning for office personnel’ s own next steps in improving recruitment



Preliminary Results: Use of Guide by 8 “Pilot” Society offices

- 2/8 offices in communities without Academic Health Centers
- The pilot Society offices:
 - used the processes in Guide to convene discussion with staff about recruitment of volunteers
 - reported steps and worksheets in the Guide encouraged them to take an approach that best fits their context
 - liked the 6 scenarios illustrating how recruitment *could* be supported (vs. being presented as guidelines)
 - found at least one scenario particularly relevant for them, yet reported being encouraged to think broadly by the other five



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