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RESEARCH GUIDING CLINICAL INTERVENTIONS IN OLD AGE – MIND THE GAP

Despite the fact that medical diseases and functional decline disproportionately affect older adults, most participants of clinical trials (RCTs) are relatively young. Despite the global and well-recognized shift in population structure implying more people living longer lives, there is still a misrepresentation of older patients in relevant clinical trials. Thus, the health system is required to manage the medical and psychological problems of common chronic diseases and frailty – health related problems experienced by older adults, without an empirically tested knowledge base.

The evidence bases for geriatric medicine and clinical geropsychology are reliant on extrapolation from clinical trials completed on younger populations. It has long been maintained, from researchers as well as clinicians, that older adults are systematically

excluded from randomized controlled trials of new interventions of drugs, psychologically founded treatments, and health-risk behaviours. This is attributable to various barriers, related to the specific trial being conducted, or to the researcher/therapist, and not least to the patients themselves. We maintain, however, that chronological age may not be the best measure of defining who is eligible or not to take part in clinical trials.

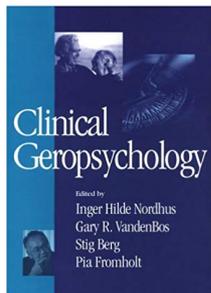
Generally, clinical trials do not limit eligibility based on age alone, and criteria related to severity of the disease and eventual comorbidities are most often among the critical exclusion criteria in the effort of sampling a homogeneous group in terms of their health profile. In an early phase of the study, for instance, commonly described as “proof of concept” studies, heterogeneous groups are conceived of as ineligible. Homogeneous samples are therefore preferred to avoid treatment effects that may be attenuated by adverse reactions to comorbid disease, drug interactions and differing pharmacokinetics of drugs in older people. Although these are logical exclusion criteria in one sense, they still limit enrolment of older persons in clinical trials – more or less by default. Besides, we should bear in mind that in clinical practice older patients generally have a higher number of comorbidities than their younger counterparts, and they often suffer from a combination of active medical problems necessitating respective medical treatments. Moreover, in addition to excluding older patients by age, clinical trials do not necessarily include adequate methods for, nor focus on evaluating more thoroughly, functional status suited for assessment of the older patient. Therefore, it should follow that researchers should more systematically focus on how specific functional measures can provide both relevant and valid information of individual health status – whether the patient is old or young.

The clinical researcher is trained as a health professional in his or her respective discipline as well as being trained as a researcher. The perception of one’s role may thus be complicated. You want to adhere to your strict “scientific mind” and you also acknowledge that your study should be relevant for those suffering from the specific health problem(s) you focus on. The biological changes of ageing, as well as the risk of polypharmacy followed by pharmacokinetic challenges, do require more extensive monitoring of the intervention and how treatment is tolerated – medically and psychologically. The solution is not to exclude patients by old age; but rather increase the number of trials aimed at older patients, and adapt our trial protocols to fit the needs of this target population. How? By designing protocols specifically written with this aim in mind.

Taking part in a clinical trial, implies considering that participation means a lack of autonomy over treatment choice, and both the older patient and his or her family members may therefore decline for the patient to enrol in a clinical trial. This and other perceived challenges by the patient may include whether the patient understands the benefits of the clinical trial and also the logistic and practical problems and solutions of clinical trial enrolment. Participation may require patients to travel, and older patients may have restricted mobility and a more limited support network as compared to younger counterparts. Still, ensuring that the trials are well understood by the patient and are accessible are equally important with any study population. It may imply, however, that additional research staffing may be needed to account for eventual extra time and resources required for enrolling older patients. When needed, an increase in logistical support seems to be a key feature in attracting more older patients to clinical trials.

What conclusion then might we draw as psychologists, and where do we go from here?

- Geriatricians and geropsychologists/psychologists in geriatric practice serving older people, need high quality evidence;
- We need better predictors of an older cohort than age alone; functional decline increases with increasing age, but not in a linear fashion;
- Better indexes/measures of health/frailty can facilitate trials and generate reliable RCT data to guide future clinical practice in a rapidly ageing society;
- Researcher bias/perception can contribute as impediments to enrolment of older person in clinical trials;
- We need a shift in focus (culture) among researchers and research institutions to boost trial enrolment of older patients;
- Eligibility and availability to RCTs are critical when older adults are omitted from empirically tested treatment; a problem faced by both patients and health care professionals.



Inger Hilde is passionate about many areas of research within geropsychology, including insomnia, pain, late-life anxiety, evidence-based treatments and nursing home populations. She published one of the first edited volumes on clinical geropsychology in our field (1998). She is committed to creating stimulating research environments for early career researchers in the field of ageing research.