Does the Well Elderly Intervention work? How data analysis techniques can change the answer

Research Objectives
The research of David Schelly and Alisha Ohl centers on evidence-based practice and health behaviour.

Detail
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Bio
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Dr Ohl received a PhD in Occupational Therapy from New York University in 2012 and is the Chair and Program Director of the Occupational Therapy Program at Clarkson University.

References

Personal Response
What further research is needed to better understand the efficacy of the Well Elderly Intervention?

It is still possible that “Lifestyle Redesign” prevents age-related declines, but Well Elderly studies have traditionally relied on a crossover design, where the control group receives treatment after the treatment group’s treatment has ended. Thus, there is no way to continue comparing the two groups over time. Of course, it is difficult to recruit participants if they have a 50% chance of receiving no treatment (as opposed to receiving it later). Future research should randomise participants into two treatments: one-on-one occupational therapy treatment in one group, and group sessions and community outings in the other, with objective measures of health repeated over many years.
The Well Elderly Intervention is a behavioral intervention aimed at older adults, over the age of 60. It focuses on building a healthy lifestyle to prevent chronic health conditions that are more common in later life, such as depression.

The Well Elderly Intervention was developed in the United States during the 1990s and has been found to be more beneficial to physical and mental health outcomes than other approaches. Accordingly, the Well Elderly Intervention is now being adopted in other countries such as Scandinavia and the UK. Notably, the Well Elderly studies led the UK’s National Institute for Health and Care Excellence to add a guideline for occupational therapy services in community settings.

The Well Elderly II study was conducted in 2012 to build upon the original research by testing the effectiveness of the intervention among even more ethnically diverse elderly population.

**The GOLD-STANDARD**

To establish the effectiveness or efficacy of an intervention, researchers often use randomized controlled trials (RCTs). RCTs are the gold standard of study design. Dr David Schelly, Assistant Professor in the Department of Occupational Therapy at Clarkson University explains: “At their best, RCTs allow us to establish a causal connection between a given treatment and outcome.” The random allocation of individuals into different groups (e.g., treatment and control) evens out inherent differences in the groups, making them equal. Once the groups are equal, we can conclude that any post-treatment differences between the groups are associated with the treatment.

The best way to analyze RCT data, and the only way to preserve the benefits of randomization, is using “intent-to-treat” (ITT) analyses. ITT involves including analyses of all individuals who were randomly assigned to each group at the start, regardless of whether they dropped out, changed groups, or received different levels of treatment to others in their group.

However, if groups are not equal in the level of treatment received, it can be difficult to reach conclusions about the effectiveness of the intervention. This highlights an issue with using only ITT analyses to determine the effectiveness of an intervention, especially in relation to preventative interventions.

Preventative interventions such as the Well Elderly are aimed at healthy people. However, research has found that healthy individuals are much more likely than unhealthy individuals to drop out of treatment or skip treatment sessions. In the Well Elderly II, for example, 30.6% of those who were randomized into the treatment group never attended an individual treatment session. This creates substantial imbalance in the groups, whereby people with more severe symptoms at the start will receive a higher “dose” by attending more treatment sessions and therefore may have better outcomes. Therefore, it may be useful to conduct follow-up analyses whereby individuals are grouped as they were treated (“as-treated analyses”). Unlike ITT, as-treated analyses focus on treatment actually received. While the approach necessarily abandons the benefits of RCT data, where intergroup differences are washed away during randomization, it also provides a snapshot of treatment efficacy, or whether a treatment actually works.

**The CURRENT RESEARCH**

The Well Elderly II study reported that the invention led to significant improvements in several health outcomes, including general health, mental health, life satisfaction and depression. However, because the Well Elderly Intervention is a preventative treatment programme which enrols many healthy individuals, there is a high rate of non-adherence to the intervention.

The authors of the Well Elderly II study used ITT analysis, but they did not follow-up with an as-treated analysis. Given that there is a high rate of non-adherence to the intervention by healthy people, their results might be different when investigating individual outcomes based on their treatment (as-treated) rather than original group allocation (ITT).

To investigate this, Dr David Schelly and Dr Alisha Ohl of Clarkson University conducted an as-treated analysis of the Well-Elderly II study data. They wanted to understand what dose of therapy, and in what form, is needed to experience improvements in symptoms of depression.

Using advanced statistical methods in a large sample of 322 participants, they investigated three modes of treatment in the Well-Elderly II study, including individual therapy sessions, group therapy sessions, and community outings, to consider the effects of treatment on depression outcomes.

**FINDINGS**

Dr Schelly and Ohl found that the benefits of the Well Elderly II study might not be as straightforward as originally reported. Overall, there was a small decrease in depression symptoms after treatment, which concurs with the original research. However, when looking at the unique influence of each treatment programme along with potentially confounding factors, no mode of treatment had a direct effect on depression outcomes.

More detailed exploration of the data showed that individual sessions and community outings had small indirect effects of depression by increasing “activity frequency,” which then slightly reduced depression scores. There was no indirect effect of group sessions on depression.

A “selection effect” was present for individual treatment, where individuals with higher depression scores at baseline were the most likely to participate. One reason for this may be that individual sessions attract people with more depressive symptoms whereas healthier individuals choose not to attend the sessions. This selection effect has important implications because the programme is meant to target healthy individuals.

As Well Elderly was designed as a preventative treatment, its target participants would have lower depression scores at the start, making improvements in scores more difficult. Furthermore, the results of the study suggest that for individuals with high depression scores, community outings are as effective as individual sessions, but require much less professional training to staff. Individual and group sessions with occupational therapists are expensive, and there is no evidence of intervention effectiveness when a small number of individuals experience large improvements, but the majority of individuals improve very similar to the control group. When the large improvers are in the extremes at baseline (e.g., high depression scores), their improvement may be in part because of regression to the mean.

Further research by the team also recommends that researchers avoid using significant p-values as indicators of intervention effectiveness. The researchers show that statistical significance can often have little real world relevance, and that measures of clinical relevance are more appropriate for assessing intervention effectiveness. This highlights the importance of using the most appropriate methods of statistical analysis and interpretation to determine the true effectiveness of an intervention. While the gold standard is to use ITT to analyze RCT data, it is often appropriate to conduct follow-up analyses to assess treatment effectiveness.

Healthier people are much more likely to drop out of treatment or skip treatment sessions.