Clin. Invest. (2012) 2(2), 129–131

CLINICAL INVESTIGATION

NEWS

Community-based study highlights the importance of recruiting homeless persons in smoking cessation trials

A community-based randomized clinical trial conducted in Minnesota (MN, USA) highlights the importance of designing smoking cessation intervention studies for the unique needs of the homeless population

The prevalence of smoking remains high among the homeless populations. Approximately 70% of homeless persons are known to smoke, which is three-times the national USA average; however, smoking cessation studies usually exclude the homeless population. Therefore, novel evidence-based interventions are needed for this high-risk subpopulation of smokers.

With this in mind, scientists at the University of Minnesota (MN, USA), Albert Einstein College of Medicine (NY, USA), University of Michigan (MI, USA), University of California Los Angeles (CA, USA) and Wilder Foundation (MN, USA) aimed to design the first ever smoking cessation clinical trial in the homeless population. The study, a two-group randomized community-based trial, enrolled 430 participants residing across eight homeless shelters and transitional housing units in Minnesota (MN, USA). The study aimed to test the efficacy of motivational interviewing for enhancing adherence to nicotine replacement therapy (NRT; nicotine patch) and smoking cessation outcomes.

The participants were randomized to one of two groups; active (8 weeks of NRT + six sessions of motivational interviewing) or control (NRT + standard care). Over 6 months participants attended six in-person assessment sessions and eight retention visits at a location of their choice. Over the first 8 weeks of the 26-week trial, nicotine patches were administered in 2-week doses at four visits. The primary outcome was cotinine-verified 7-day point-prevalence abstinence at 6 months. The secondary outcomes included adherence to nicotine patch, assessed through patch counts and direct observation. Other outcomes were listed as the mediating and/or moderating effects of comorbid psychiatric and substance abuse disorders.

The results, published in *Clinical Trials*, highlighted several 'lessons learned' in order to help improve the recruitment of the homeless population:

- Forming and convening a Community Advisory Board in order to engage the perspectives of shelter leadership;
- Locating studies at the shelters in order to increase visibility and provide easier access for participants;
- Minimizing exclusion criteria, allow enrollment of participants with stable psychiatric comorbid conditions;
- Protecting against attrition by delaying the baseline visit from the eligibility visit by a week.

The researchers clarified the study limitations, discussing the issue of generalizability due to the sample drawn from a single Midwestern city in the USA, and that all participants were already motivated to quit smoking at the time of enrollment in the study since inclusion criteria encompassed willingness to use NRT patch. Therefore, findings from the self-select group in the study are generalizable only to those motivated and ready to quit smoking and high incentives may limit the degree to which the intervention is replicable.

Nonetheless, the authors were positive about the results and the study has provided important lessons for improving recruitment and retention in the homeless population. The authors concluded that the lessons learned "reflect the need to engage communities in the design and implementation of community-based clinical trials with vulnerable populations" and have provided important insights into this mobile and vulnerable population.

Written by Ruth Williamson, Assistant Commissioning Editor.

Source: Goldade K, Whembolua GL, Thomas J *et al.* Designing a smoking cessation intervention for the unique needs of homeless persons: a community-based randomized clinical trial. *Clin. Trials* 8(6), 744–754 (2011).

ISSN 2041-6792
10.4155/CLI.11.177

Exonhit announce observational study for AclarusDx®

Exonhit have announced a study to investigate the effectiveness of the test for Alzheimer's disease

Exonhit, a biotech company whose main focus is personalized medicine, have recently announced the launch of an observational study to evaluate the efficacy and performance of AclarusDx®. Exonhit, whose headquarters are in Paris, France, began recruiting patients for the study in December and will be performing the study within France.

AclarusDx is a diagnostic test designed to assist in the diagnosis of Alzheimer's disease, the test is blood based and is used in specialized memory centers. The test is used when patients are assessed for the first time for Alzheimer's disease. The observational study has been named DIALOG and is to be sponsored by Exonhit.

Alzheimer's disease is a condition characterized by progressive cognitive decline and is a common form of dementia. There is currently no cure for the disease and treatments are usually targeted at slowing the progress of the disease or at controlling symptoms. For these reasons early diagnosis is beneficial to individuals as many sufferers can remain undiagnosed for several years, with symptoms being mistaken for age-related mental decline. The earlier an individual is diagnosed and can receive treatment for the condition, the better the therapeutic outcome.

> "The development of a blood-based test would be extremely beneficial in terms of patient comfort and ease of use."

The current methods of diagnosis for the condition involve clinical investigation, examination of behavior, psychometric tests and additionally brain imaging. Biological markers have been identified and can be measured in cerebrospinal fluid; however, this method is invasive. The development of a blood-based test would be extremely beneficial in terms of patient comfort and ease of use.

The study is expected to enroll 600 patients being assessed for the first time at two specialist memory centers based in France, the Centres Mémoire de Ressources and de Recherche or Consultations Mémoire. Patients suffering from cognitive disorder and/or memory impairment will be assessed using the AclarusDx test and will be followed up after the initial diagnostic work-up. Follow-up data will be collected at 6 months and 1 year after the initial visit

The President of the Scientific Advisory Board, Françoise Forette, is hopeful of a positive outcome from the study, commenting, "This is an important step in the life-cycle of AclarusDx. This study will allow the medical community to position AclarusDx within the AD diagnostic work-up, while diagnostic criteria are still evolving."

Written by Cara Sutton, Managing Commissioning Editor.

Source: Exonhit press release: www.exonhit.com/sites/default/files/PR_EHT_Dx21_DIALOG_09_Dec_2011_EN_0.pdf

Novartis latest in line to shut down brain research facility as pharmaceutical companies look to investigate alternative avenues

Novartis has closed down its neuroscience facility in Basel, Switzerland, but plan to open a new division focused on studying the genetics of psychiatric and cognitive disorders in the hope of identifying new treatment targets

Following similar moves by GlaxoSmithKline and AstraZeneca, Swiss-based drug giant Novartis has closed its neuroscience facility in Basel, Switzerland. The move signals the end of more traditional drug-discovery programs aimed at pursuing treatments for brain disorders. Other companies to similarly pull back on research into this area include US-based companies Pfizer and Merck, as well as Sanofi, based in France.

Due to recent failures after years of clinical trial testing, developing drugs for brain disorders has become a risky venture for many pharmaceutical companies. This is not eased by the fact that the current market is saturated with cheap generic antidepressants, antipsychotics and other drugs that act on targets in the brain. These factors have led many pharmaceutical companies to pursue alternative avenues and attempting to identify novel drug targets. So far this search has proved difficult as little is currently known about the biology of the brain and its disorders.

"Standard approaches to developing drugs for mental health have not reaped significant benefit in the past two decades," commented Ken Kaitin, Director of the Tufts Center for the Study of Drug Development (Boston, USA). He continued, "But it is a dilemma for the companies because there is a large and growing market for these products."

> "Due to recent failures after years of clinical trial testing, developing drugs for brain disorders has become a risky venture for many pharmaceutical companies."

Rather than abandoning its neuroscience research altogether, the Novartis

Institutes of Biomedical Research are planning to open a new division at its site in Cambridge, MA, USA, aimed at studying the genetics of psychiatric and cognitive disorders in the hope of eventually identifying new treatment strategies. In addition, the companies hope to be able to find genetic biomarkers that will enable them to identify individuals who are more likely to respond to a particular drug. "It's the basis of personalized medicine – health plans are more likely to pay for a new drug if they are convinced it will work for the person it is prescribed for," explained Kaitin.

Stephen Stahl, a psychopharmacologist and psychiatrist at the University of California (San Diego, USA), also explained that some companies are attempting to use gene sequencing in order to look for new targets. "GlaxoSmithKline pulled out of traditional CNS pharmacology but is pursuing research into neurodegeneration at its new sequencing centre in Shanghai," he analyzed. No-one yet knows how successful this promising approach may be.

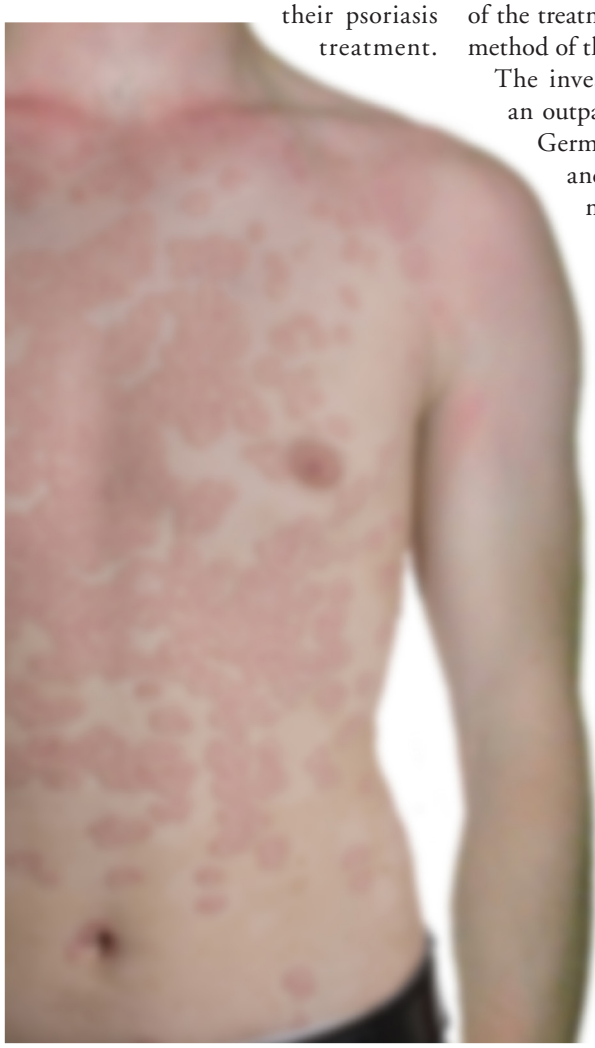
Written by Paolo Reveglia, Commissioning Editor.

Source: Abbott A. Novartis to shut brain research facility. *Nature* 480(7376), 161–162 (2011).

Psoriasis treatments: convenience outweighs outcome

When considering a psoriasis treatment, the importance of process outweighs the outcome

Researchers from the Heidelberg University (Mannheim, Germany) have investigated what patients believe to be the most important attributes to consider when choosing their psoriasis treatment.



It was found that patients thought that the compatibility of a treatment with their life style was the most important attribute of a treatment, followed by the probability of the treatment having a benefit and the method of the treatment delivery.

The investigation was carried out at an outpatient dermatology clinic at a German university medical center and involved 163 patients with moderate to severe psoriasis. The treatment attributes were defined into two categories; outcome (adverse effects, probability magnitude and duration of benefit) and process attributes (treatment location, frequency, duration, delivery method and cost to individual). A computer-based conjoint analysis experiment was conducted and relative importance scores (RIS) for each attribute were calculated. The RIS were assessed using analysis of variance, *post hoc* testing, and multivariate regression analysis.

The attribute considered to be most important in patients' preferences for psoriasis treatments was treatment location (RIS: 26.76), followed by probability of benefit (RIS: 23.77) and method of delivery (RIS: 23.49). The RISs for all process attributes were higher than for adverse effect-related attributes. Older individuals (aged 65 years) were less concerned about the probability of benefit when compared to younger individuals.

The authors conclude that when considering the treatment options for their psoriasis individuals will prioritize the convenience of a treatment over the effectiveness of a treatment, and that incorporating preferences into shared decision making about treatment options may facilitate treatment adherence and optimize outcome.

Written by Bianca Benn, Assistant Production Editor.

Source: Schaarschmidt ML, Schmieder A, Umar N *et al.* Patient preferences for psoriasis treatments. *Arch. Dermatol.* 147(11), 1285–1294 (2011).

The editorial team welcomes suggestions for timely, relevant items for inclusion in the news. If you have newsworthy information, please contact:
Cara Sutton,
Managing Commissioning Editor, *Clinical Investigation*
Tel.: +44 (0)20 8371 6090;
E-mail: c.sutton@future-science.com