Improving Transparency of Clinical Trial Data

Practical Issues for Patients, Family and the Public

Availability ~ Accessibility ~ Intelligibility

Stop Gaps ~ Implications

Doris A. Fuller
Chief of Research & Public Affairs
Treatment Advocacy Center
My daughter, who lost her battle with mental illness, is still the bravest person I know.
Longer-term outcome in the prevention of psychotic disorders by the Vienna omega-3 study

G. Paul Amminger¹, Miriam R. Schäfer¹, Monika Schögelhofer², Claudia M. Klier³ & Patrick D. McGorry¹

Long-chain omega-3 polyunsaturated fatty acids (PUFAs) are essential for neural development and function. As key components of brain tissue, omega-3 PUFAs play critical roles in brain development and function, and a lack of these fatty acids has been implicated in a number of mental health conditions over the lifespan, including schizophrenia. We have previously shown that a 12-week intervention with omega-3 PUFAs reduced the risk of progression to psychotic disorder in young people with subthreshold psychotic states for a 12-month period compared with placebo. We have now completed a longer-term follow-up of this randomized, double-blind, placebo-controlled trial, at a median of 6.7 years. Here we show that brief intervention with omega-3 PUFAs reduced both the risk of progression to psychotic disorder and psychiatric morbidity in general in this study. The majority of the individuals from the omega-3 group did not show severe functional impairment and no longer experienced attenuated psychotic symptoms at follow-up.
ACCESSIBILITY

How Can the Use of Evidence in Mental Health Policy Be Increased? A Systematic Review

Anna Williamson, B.Psych.D. Steve R. Makkar, B.Psych.D. Catherine McGrath, LL.B. M.Phil.
Sally Redman, B.A.(Psych.) Ph.D.

http://dx.doi.org/10.1176/appi.ps.201400329

Your Access Options

Log In
If you have an individual subscription to this content, or if you have purchased this content through Pay Per Article within the past 24 hours, you can gain access by logging in with your username and password here:

Username: 
Password: 
Login

Purchase $35.00
Add to cart

Forgotten your password?
Register
(63 with participants, 4 with next of kin) for 82.7% (67/81) of participants and hospital records for 4.9% (4/81). Of those with no longer-term data, six were from the omega-3 PUFA group and four from the placebo group. None of them has received psychiatric treatment according to a Vienna-wide electronic register of health service utilization since their initial presentation. According to the National Death Index, no participant had died.

The cumulative conversion rate to psychosis at the longer-term follow-up was 9.8% (4/41) of subjects in the omega-3 PUFA group, and 40% (16/40) of subjects in the placebo group. The difference between the groups in the cumulative risk of progression to psychosis was 30.2% (95% confidence interval, 10.1–50.4, with continuity correction). Figure 1 shows the SCID-based DSM-IV lifetime diagnoses of the psychotic patients at longer-term follow-up. The survival times were significantly different between the treatment groups, with a more rapid conversion time for the placebo group compared with the omega-3 PUFA group (log-rank test: $\chi^2=9.84$, $P=0.002$) (Fig. 2). A sensitivity analysis assuming all cases that had no longer-term follow-up information would have developed psychosis was consistent with the intention-to-treat analysis (log-rank test, $\chi^2=5.18$, $P=0.02$).

Figure 2: Kaplan–Meier estimates of the risk of progression from the at-risk state to psychotic disorder in participants assigned to omega-3 PUFAs or placebo.
STOP GAPS - Availability

Google Scholar

Tip: Quickly lookup references

Stand on the shoulders of giants
STOP GAPS - Accessibility

Longer-term outcome in the prevention of psychotic disorders by the Vienna omega-3 study

G. Paul Amminger, Miriam R. Schäfer, Monika Schögelhoefer, Claudia M. Klier & Patrick D. McGorry

Nature Communications 6, Article number: 7934 | doi: 10.1038/ncomms8934
Received 26 November 2014 | Accepted 29 June 2015 | Published 11 August 2015
The Growing Focus on Inflammation in Psychiatric Research

Two theories have for decades dominated research on the causes of schizophrenia: genetics and neurotransmitters. Over the past two years, a third theory – the infectious/inflammatory theory – has become the first major new addition to schizophrenia study in the last half-century and, with less evidence, to the study of bipolar disorder and depression.

This theory states that infections play an important role in causing schizophrenia, probably in conjunction with predisposing genes or the effects of infectious agents on neurotransmitters. Evidence of the growing focus can be seen in the recent outpouring of professional papers proposing to use anti-infective and anti-inflammatory drugs to treat schizophrenia and bipolar disorder (see figure). Also indicative is the emergence of infectious/inflammatory theory in mainstream scientific media and books, including Infectious Madness: The Surprising Science of How We "Catch" Mental Illness, by science writer Harriet Washington (Little, Brown, 2015).

Now in Treatment Trials

The Stanley Medical Research Institute (SMRI), a supporting organization of the Treatment Advocacy Center, has been funding research into the role of infection and inflammation in the causes of and treatment for schizophrenia for more than 20 years. Half of SMRI’s current 52 treatment trials involve the use of anti-infective or anti-inflammatory agents/drugs to alter the immune system. Slightly more than half of its newly funded trials also will be testing anti-infective or anti-inflammatory agents in the treatment of schizophrenia.

An example is Valacyclovir, an antiviral widely used against herpes family viruses. In 2014, a small SMRI trial reported improved cognitive functions of individuals with schizophrenia; a much larger replication trial is in progress using 12 American sites. Treatment trials also are underway utilizing anti-inflammatory drugs (e.g., aspirin) specifically on patients with schizophrenia who have elevated levels of inflammatory markers in their blood (e.g., high C-reactive protein). The aspirin study will be completed in mid-2016.
IMPLICATIONS
Using Evidence to Influence Policy and Improve Practice

Michael Hogan, Ph.D.

Former Surgeon General David Satcher—the first Surgeon General to focus deeply on mental health—often lamented “the gap between what we know and what we do” in mental health care. His complaint resonated with advocates and stakeholders, who know that the quality of care should be better. However, despite the momentum generated by the Surgeon General’s 1999 mental health report, strong emphasis on closing the science-to-service gap in the 2003 report of the President’s New Freedom Commission on Mental Health, and a few notable exceptions such as the Department of Veterans Affairs campaign to promote evidence-based psychological services, there is little evidence that the gap has closed. Therefore, the thoughtful and competent review by Williamson and colleagues on interventions and strategies to increase the use of evidence to improve mental health policy, which appears in this month’s issue, is salient.

A careful reading of this review and a consideration of the status of the field indicate that we are facing a chasm, not a mere gap. Williamson and colleagues’ literature search returned 2,077 citations, and the authors identified an additional 50 relevant papers by scanning reference lists. After weeding out unpublished articles, studies in which an intervention was not tested, and studies that did not include policy makers as part of the intervention, a total of nine qualifying studies were found! Given the scope and public health impact of the science-to-service gap, this is on the scale of fighting a five-alarm fire with a garden hose.

Is this a bit melodramatic? After all, there have been many efforts to promote adoption of evidence-based team interventions for individuals with severe mental illness. Despite these efforts, it is still able to only a small fraction of adults. For example, despite the purported employment, this is only about 29% of adults with mental illness. According to the researchers Gary Bond and others, the availability of an intervention model in common mental disorders studied in more than 80 to 90% spread of collaborative care elements with long-term availability of this intervention population that could benefit from it.

The urgency of the effort is implementation of proven interventions, which makes it essential to be very timely. The promise of federal investments in roles such as the supported employment (Johnson) by the virtual absence of this intervention population that could benefit from it.

We are now seeing a trend within mainstream mental health care: Medicaid where financing is provided to care for authorities that may have treatment technology. It is “policy mainstreaming” of government evidence-based innovations toward mental health, but also toward the best evidence.
IMPLICATIONS

The Effect of Family Interventions on Relapse and Rehospitalization in Schizophrenia: A Meta-Analysis

Gabi Pittschl-Waltz, Stefan Leucht, Josef Bauml, Werner Kissling, and Rolf R. Engel
IMPLICATIONS