Chronic Fatigue Syndrome

What have we learned from 17 years of research

Dr Mark Donohoe, CEBCoM

A speech is a solemn responsibility. The man who makes a bad thirty-minute speech to two hundred people wastes only a half hour of his own time. But he wastes one hundred hours of the audience's time - more than four days - which should be a hanging offence.

Jenkin Lloyd Jones

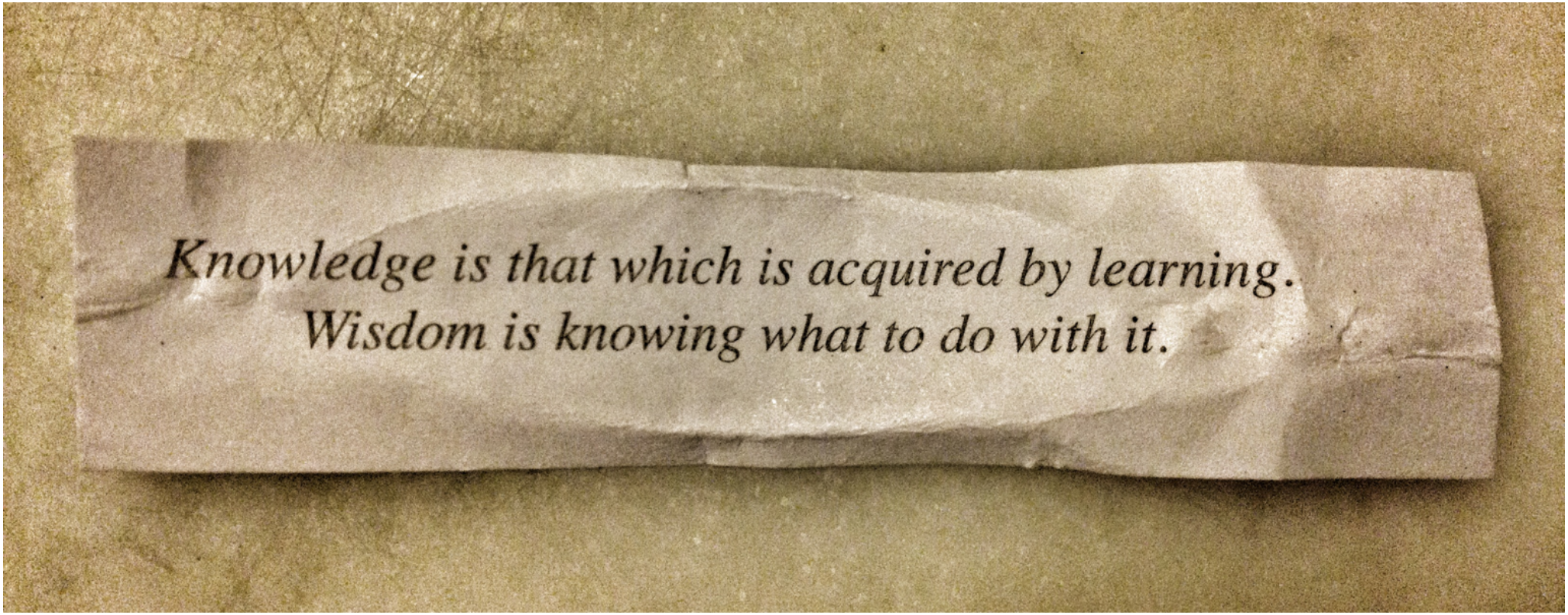
Free Will in Dunedin

Robbie Burns
David Hume

Free Willy in Dunedin

Personal story

- **I Come In Peace** as a half-blood Kiwi
- I suffered a CFS-like illness in 1994-1996
- Involved in practice and research in CFS 25 years
- Started move to evidence-based practice 5 yrs ago
- Went for "active treatment" in place of care
- Result? 3 suicides and obviously worse outcomes
- Don't need a RCT to know when you've f^%$ up!


Knowledge is that which is acquired by learning.
Wisdom is knowing what to do with it.

The time comes when you realize that you haven't only been specializing in something - something has been specializing in you.

Arthur Miller

My Medical practice and research has spanned the 24 years of definitions & research.

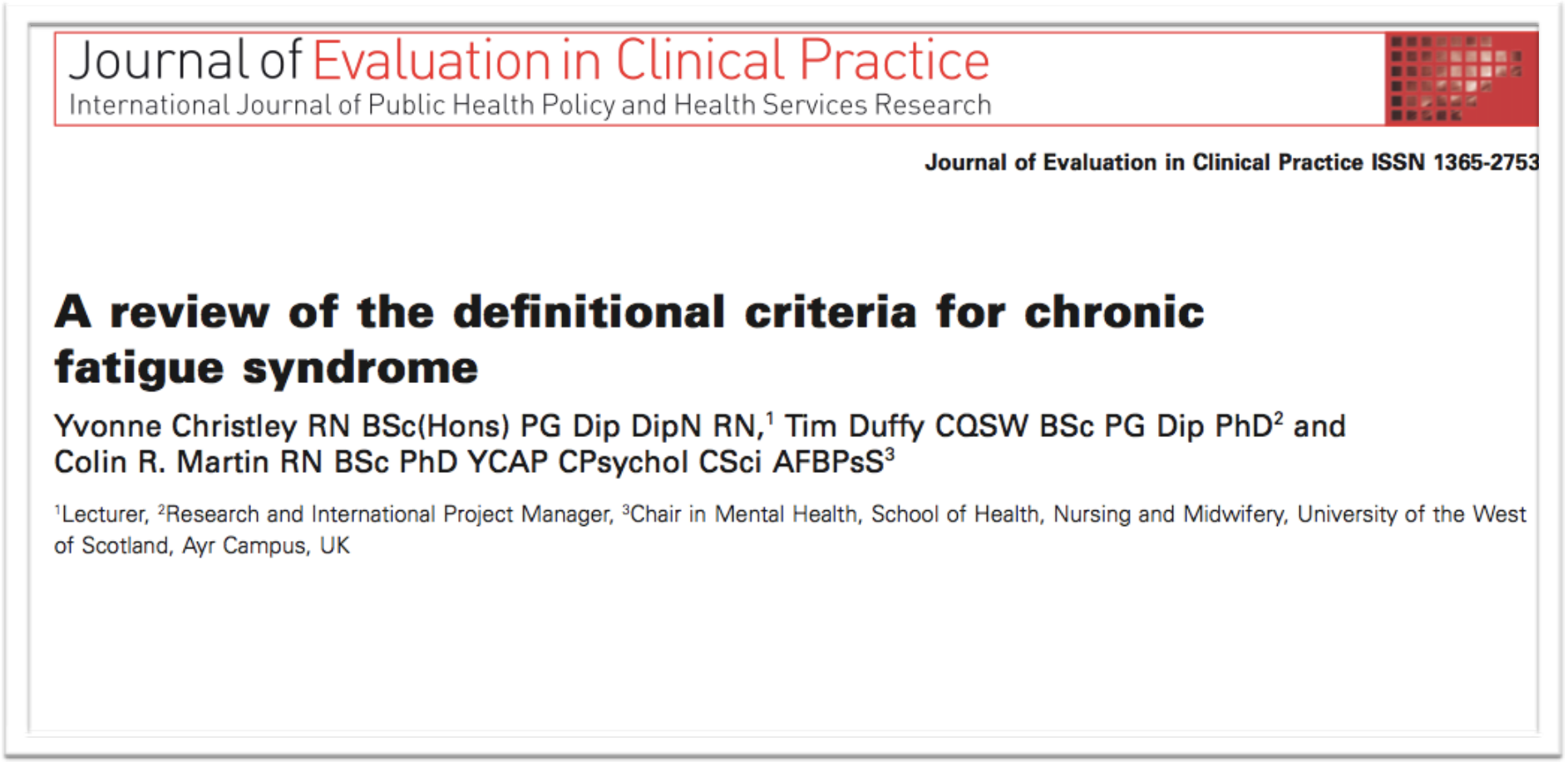
I've lived it and applied it.

Problem # 1

Multiple CFS Definitions

Review of CFS Definition

Journal of Evaluation in Clinical Practice **18** (2012) 25–31



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A review of the definitional criteria for chronic fatigue syndrome

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The six main case definitions

- CDC 1988 case definition (Holmes et al)
- Australia 1990 (Lloyd et al)
- Oxford 1991 guidelines for research (Sharp et al)
- CDC 1994 case definition (Fukuda et al)
- Canadian CFS definition, Dx and Tx protocols
- CDC 2005 empirical definition (Reeves et al)

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Only 1 addresses treatment

- CDC 1988 case definition (Holmes et al)
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CDC 2005 definition *(Reeves et al)*

"Despite the public health burden imposed by CFS, effective diagnostic, treatment and prevention strategies are not available **because** the etiology, risk factors and pathophysiology of CFS remain unknown"

REALLY?

General Practitioners work with that impaired knowledge-base and uncertainty every day and with almost every patient, and do fine

Outcome of the Definitions

- Lots of research loosely tied to case definitions
- “More research is needed” as conclusion for all
- Little clinically useful information for GP
- Precious little benefit for the sufferers
- A diverse group with a common problem of fatigue are corralled into the one category for the purpose of performing poor research

Why has Chronic Fatigue Syndrome not yielded to science, research and EBM?

Because Chronic Fatigue Syndrome is not a single disease, illness or entity.

Because Chronic Fatigue Syndrome sufferers refuse to control their variables

Because Chronic Fatigue Syndrome sufferers choose a variety of health professionals

Because Chronic Fatigue Syndrome has many origins, many expressions and many endpoints and outcomes

Because Chronic Fatigue Syndrome sufferers are not participating in an RCT

Because Chronic Fatigue Syndrome involves meaning, suffering, community, acceptance, and compassion, and these are difficult variables to control for

Problem # 2

Case definitions and EBM
Can do harm

What harms

- Too much reading and work and red tape for Drs
- Clinical Practice Guidelines made by experts
- Demands of insurers to justify all care
- Cost-cutting of all practices not EBM blessed
- Practice audits to make sure we are compliant
- No place for outcomes of each person

Let’s step back a bit

Let's step back a bit

When was the last time an RCT *actually* applied to the patients you see each day?

RCTs and EBM

- Complex, complicated and expensive but “neat”
- Designed and run usually by academics
- Controlled for variables
- Statistical in nature - one protocol for many
- Reduce complexity of individuals to zero
- Have no interest in difference between outcomes

General Practice

- One at a time, messy and imprecise
- Run in time constraints by overworked GP
- All variables uncontrolled
- Individual in nature - what's best for *this* patient
- Individual complexity and needs very high
- Iterating towards best outcomes, often blindly

Epidemiologists know it too

J Clin Epidemiol Vol. 51, No. 4, pp. 289–295, 1998

PII

Commentary

Incommunicable Knowledge? Interpreting and Applying the Results of Clinical Trials and Meta-Analyses

George Davey Smith and Matthias Egger*

Department of Social Medicine, University of Bristol, Bristol, United Kingdom

Assessments of medical therapeutics must grapple with the distinction between general principles—the benefits (or harm) which treatments produce at the group level—and decisions about the particular form of clinical care that an

cies that the doctor must treat. Fo
remain entirely out of the questio

The viewpoint illustrated here was c

CFS Questions us as Doctors

- A challenging novel type of illness
- No easy answers, sometimes no answers at all
- How do we act when we feel powerless to relieve?
- Who do we turn to? Experts? Internet
- Does “EBM” do more harm than good?

Limits of EBM

Building evidence

BMJ VOLUME 327 20–27 DECEMBER 2003

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Abstract

Objectives To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Design Systematic review of randomised controlled trials.

Data sources: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.

Study selection: Studies showing the effects of using a parachute during free fall.

Main outcome measure Death or major trauma

accepted intervention was a fabric device, secured by strings to a harness worn by the participant and released (either automatically or manually) during free fall with the purpose of limiting the rate of descent. We excluded studies that had no control group.

Definition of outcomes

The major outcomes studied were death or major trauma, defined as an injury severity score greater than 15.[6]

Meta-analysis

Our statistical apprach was to assess outcomes in para-

Building evidence

BMJ VOLUME 327 20–27 DECEMBER 2003

Conclusions

As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. ....

We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.

Building evidence

BMJ VOLUME 327 20–27 DECEMBER 2003

What this study adds

No randomised controlled trials of parachute use have been undertaken

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The basis for parachute use is purely observational, and its apparent efficacy could potentially be explained by a "healthy cohort" effect

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Individuals who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump

Level II evidence

Obstetrics & Gynecology:

February 2012 - Volume 119 - Issue 2, Part 1 - p 215–219

The Comparative Safety of Legal Induced Abortion and Childbirth in the United States

Raymond, Elizabeth G. MD, MPH; Grimes, David A. MD

Abstract

OBJECTIVE: To assess the safety of abortion compared with childbirth.

METHODS: We estimated mortality rates associated with live births and legal induced abortions in the United States in 1998–2005. We used data from the Centers for Disease Control and Prevention's Pregnancy

Level II evidence

CONCLUSION:

Legal induced abortion is markedly safer than childbirth. The risk of death associated with childbirth is approximately 14 times higher than that with abortion. Similarly, the overall morbidity associated with childbirth exceeds that with abortion.

LEVEL OF EVIDENCE: II

Solid Evidence, but...

- The term “safer” needs work - safer for whom?
  - Mother, foetus, society, species?
- Will proponents of EBM go with the evidence
  - Implementing findings rigorously in own life
  - Enforce a strict “no birth” policy in practice

This year is 20 years of Evidence-based Medicine

An era can be said to end when its basic illusions are exhausted.

Arthur Miller

Dunedin 2012
Donohoe calls for end to Chronic Fatigue Syndrome Researchers

Donohoe Dunedin 2012

- No research funds without 5 years in General Practice seeing Chronic Fatigue Syndrome
- No more “case definitions” for CFS
- Approach CFS as a range of disorders of different cause, different onset, different expression and requiring individualised management
- THEN go and d your research

Donohoe 2012 Case Definition

Patient who is utterly stuffed, physically & mentally and emotionally after relatively trivial activity, stress or injury, and this goes on for days or weeks or months for no good medical reason, and who suffered no psychiatric disorder BEFORE this happened.