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Unintended benefits of a Randomised Control Trial: a demonstration of the impact of coordinated continual professional development in a remote hospital setting

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8 **Unintended benefits of a Randomised Control Trial: a demonstration of the impact of**
9 **coordinated continual professional development in a remote hospital setting**

10

11 **Abstract:** Not required for a short report.

12 **Key words:** OpTIn; Rural Health Services; Staff Development; Alcohol-related disorders; Thiamine
13 Deficiency

What is already known on this subject?

- Randomised Control Trials (RCT) are the best way to study novel clinical treatment practices.
- In any RCT there will be incidental outcomes.
- Continued professional development is essential for all health staff, particularly when working in unfamiliar contexts.

What does this study add?

- OpTIn RCT incidentally resulted in improved identification of patients with Wernicke's encephalopathy.
- The context specific, consistent education which was provided to health staff improved the care of patients.
- RCT's of pharmaceutical interventions are generally not considered to function as educational interventions; this brief report proposes that they can and should be.

14

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20 **Introduction**

21 Alice Springs Hospital (ASH) is a public teaching hospital which provides care to the population of
22 Central Australia.[1] More than 34% of the Central Australian population are Aboriginal, and Aboriginal
23 patients account for approximately 80% of ASH bed-days.[1] Many ASH staff are not Alice Springs
24 locals, and as a remote teaching hospital ASH has a high turnover of training medical staff.

25

26 Alcohol consumption in Central Australia is an acknowledged concern[2]. Excessive consumption may
27 be associated with detrimental impacts on cognitive functioning, due to Wernicke's encephalopathy
28 (WE) and Korsakoff psychosis (KP), acute and chronic phases, respectively, of Wernicke-Korsakoff
29 syndrome. Caused by a Thiamine (Vitamin B1) deficiency, the condition begins as WE and without
30 timely Thiamine treatment may progress to irreversible KP.[3]

31

32 From late 2014 to early 2019 a randomised controlled trial (RCT) was conducted at ASH to determine
33 the *Optimum* dose of parenteral *Thiamine Intervention (OpTIn)* for prevention and treatment of WE.
34 Patients presenting to the ASH emergency department (ED) who demonstrated signs of WE or had
35 an alcohol use history were screened for inclusion. Despite a previous pilot study which estimated
36 recruitment rates could be met[4], over time recruitment rates reduced, as did the study power. RCT's
37 often have unintended consequences, and we consider whether the intensive *OpTIn* staff education
38 was a factor in driving improvement of WE identification and treatment.

39

40 **Participants, methods and results**

41 Initially hospital-wide education was undertaken to ensure all clinical staff were aware of *OpTIn*;
42 particularly the consent and safety processes. Subsequently, regular face-to-face updates, education
43 at staff induction, monthly posters, and biannual newsletters addressing the clinical condition of WE
44 and Thiamine intervention were provided. Similar updates, engagement and education sessions
45 were conducted with the Aboriginal Liaison Officers.

46 *OpTIn* study design also included regular meetings with the Indigenous Reference Group (IRG),
47 consisting of community Elders, local Aboriginal health services and residential-rehabilitation
48 representatives. As a result of their involvement, IRG members developed an increased knowledge
49 of WE symptoms and treatment options.

50 Figure 1 outlines the WE and KP presentations to ASH ED from 2010-2019. As with any specific
51 disease in a remote setting, the numbers are small and thus volatile, and simple linear regression
52 analysis of this data yields a non-significant p-value (0.110). However, some increase in WE diagnosis

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from 2016 is evident. *OpTIn* education began late 2014, with strategies for education developing and improving over 2015, and, we hypothesise, reaching saturation by 2016; which coincided with changing admission capacity.

[Figure 1]

We consider the context-specific education provided to all health staff by the *OpTIn* team increased knowledge of WE and improved identification of patients who may not have previously been diagnosed due to communication and language barriers. Thus, *OpTIn* was an important factor in increasing the proactive administration of parenteral Thiamine. A number of community-based staff were also noted to request Thiamine treatment for their clients, and patients also appeared to become more accepting of their parenteral Thiamine treatment, awaiting completion of treatment before self-discharging. Minutes from IRG meeting (15/04/15) note requests for additional resources (posters) for community distribution. IRG members positions in their community as health service representatives and Elders meant they had the capacity to pass on information with authority.

Comment

RCTs are rarely considered an educational intervention, yet in the case of *OpTIn,* staff education may have been an important factor in enhancing medical care. Providing education to both tertiary and primary healthcare providers allowed for increased continuity of care. While proactive administration of Thiamine is believed to have, in part, negatively impacted the overall *OpTIn* recruitment, the unintended consequences highlighted in this paper contribute to a stronger evidence base about the benefits of ongoing, context-specific education, particularly in remote areas where the workforce is transient.[5]

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89 **Figure legends**

90 Figure 1: WE KP ASH ED presentations 2010-2019

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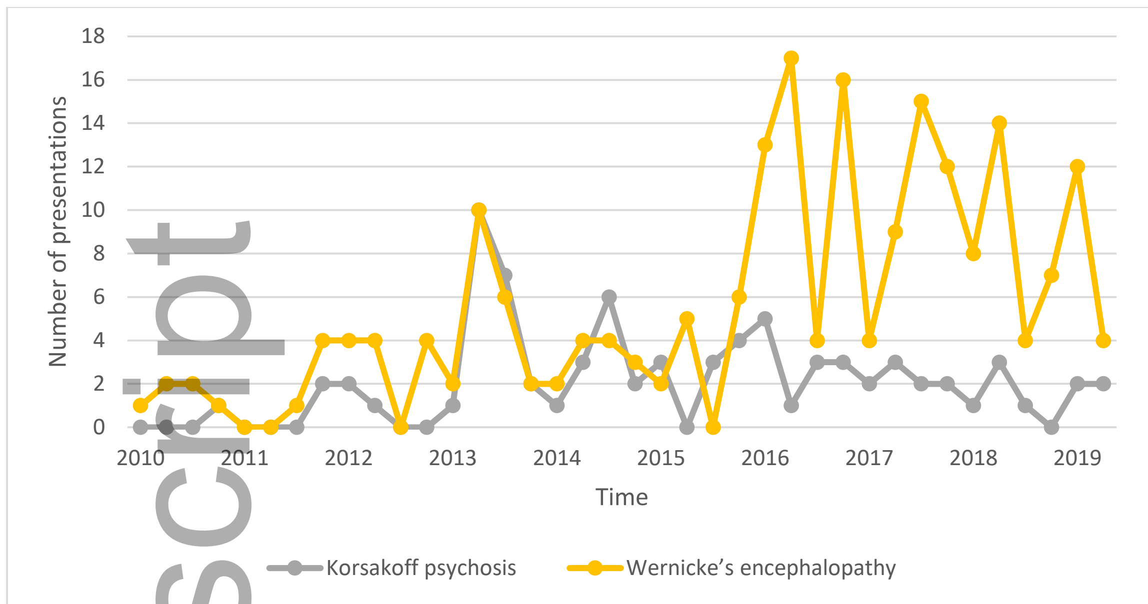

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