OpTIn – Alcohol-Cognition-Thiamine-RCT

Narrative evaluation of contextual factors on recruitment into a study on impacts of Thiamine dosage upon alcohol related neurological impairment

Jen Delima[1], Kylie Dingwall[2], Sheree Cairney[2], Gloria Baliva[2], Paula Binks[2], Stephen Bowden[3]

[1]Alice Springs Hospital, Alice Springs, NT, [2]Menzies School of Health Research, Alice Springs, NT [3]University of Melbourne, Melbourne, Australia.

Introduction

Alcohol-related brain injury including Wernicke's encephalopathy (WE) and Korsakoff psychosis (KP), often termed Wernicke-Korsakoff syndrome (WKS), may be avoided with timely and appropriate thiamine treatment.

OpTIn - A randomised controlled trial (RCT) was conducted at Alice Springs Hospital to determine the **Optimum** dose of **Thiamine Intervention** for prevention and treatment of WE.

Study duration: 4 years (2015-2018)
During the study timeframe, changes in Government policy and related legislation across health and judicial systems directly changed alcohol control and supply regulations with consequent impacts upon use-behaviours and treatment options.

Planned recruitment
- N=225 'at risk' of WE
- N=225 with initial presentation of WE

Completed recruitment data sets
- N=253 of 1012 'at risk' of WE
- N=81 of 237 with WE

The anticipated recruitment rates for patients with WE were reduced during the latter years of the research with reduced study power.

Study Aim:
1. Describe rates of WE over the study duration
2. Review contextual factors outside the study protocols and design

Two groups - WE and those at risk of development of WE were studied.

Policy changes (2014–2019)
- Alcohol Mandated Treatment Act – ceased Aug 2017
- Alcohol Protection orders –ceased Dec 2017
- Feb 2014 -POSI at Liquor outlets to 2018
- 2018 -PALI
- 2015 -Liquor Act- store licence
- Oct 2016 Moratorium on new Liquor licences
- Nov 2016 Limited Sunday alcohol trading
- Dec 2016 Floor space limit at Take away Liquor outlets
- Sept 2017 BDR reinstatement
- Oct 2018: Minimum Alcohol Floor price

ANTICIPATED CONTEXTUAL FACTORS

Population characteristics:
- Small population (27,000) hence recurrent presentations
- 26-35% Indigenous traditional culture with language/ health literacy and narrative differences

Strategy:
- ➢ 5 language interpreted consent/cognitive assessment tools
- ➢ Education of Aboriginal Liaison Officer to assist communication

Targeted patient population:
- Possible alcohol affected cognition commenced recruitment

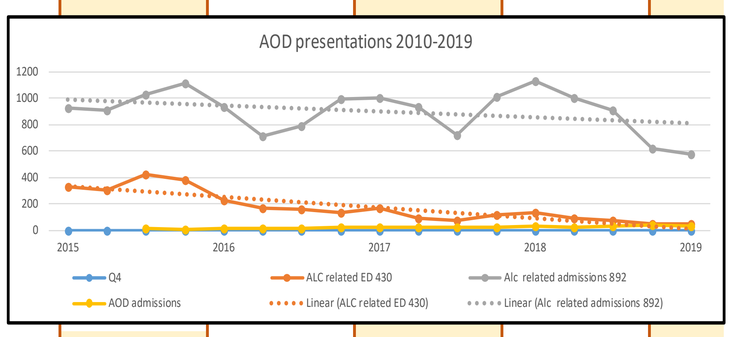
Strategy:
- ➢ Recruitment commenced with consent deferred until NOK or patient recovered well enough to provide

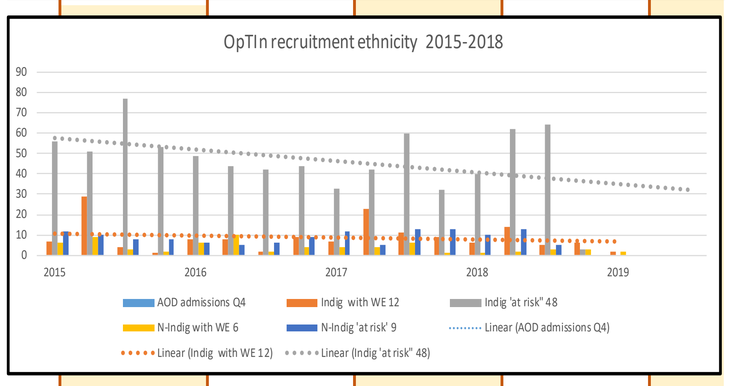
Hospital staff education:
- 3 monthly staff term changes over duration of study

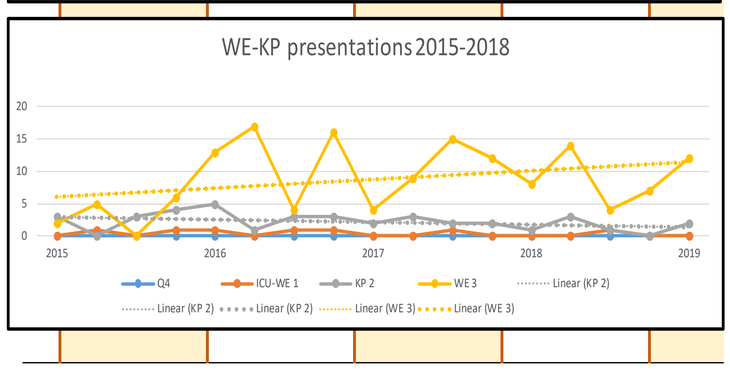
Strategy:
- ➢ Regular OpTIn education
- ➢ Video standardised assessment training for Addiction team.
- ➢ Addiction medicine assessment proformas

Results

	2014				2015				2016				2017				2018				2019	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
OpTIn Recruitment				OpTIn study																		
Hospital activities							Specific Addiction medicine admission capacity															
	Medical / Emergency dept education re Alcohol/ Thiamine																					
				Hospital wide education re: Alcohol / Thiamine																		
					Stringent Medical coding of alcohol related admissions																	
General Community			OPTIn IRG education;																			
					Residential rehabilitation and GP patient handover communication																	
Political					Alcohol Mandated Treatment per Police / Judicial direction																	
																ALP BDR reinstatement						
	Alcohol protection Orders																					
	Police POLI																PALI					
					2015 Liquor Act 'store license																	
													Oct '16 : moratorium on new liquor licences									
													Nov'16 ltd Sunday trading									
													Dec '16 ltd floor spc @ TA outlets									
																				Oct '18: Min floor pri		







UNANTICIPATED CONTEXTUAL FACTORS

Research Team:
- Remote/ regional frequent staff changes
  - ➢ Development of standardised education tools- video education
  - ➢ Dependence upon hand over procedures

Patient factors:
- Recruitment fatigue
  - ➢ Exclusion of patients after 3 recruitment cycles, to prevent assessment tool confounding
- Early self discharge "TOL" (Take own leave)
  - ➢ Cultural narrative and health literacy effects
  - ➢ Inability to complete thiamine treatment and evaluate and to later re-recruit as recently partially treated

Hospital staff education:
- Enthusiastic high dose thiamine treatment for alcohol related presentations
  - ➢ Inability to recruit to study due to confounding of dose randomisation

Improved service capacity for Addiction medicine:
- Improved management of patients with alcohol related presentations

Government Policy changes :
- Decreased presentations to Emergency department
- Mandated residential rehabilitation

Community Education:
- Community treatment programs also providing thiamine treatment

Discussion

The following factors potentially influenced study recruitment.

RESEARCH IMPACTS
- Multi year studies are more susceptible to real world dynamics

Recruitment fatigue
- **Researcher/health staff -** assertive effort required to uphold study quality
- **Patient -** acutely ill with varied cultural, narrative and health literacy needs.

HOSPITAL IMPACTS
Medical education effect – recruitment lost due to RCT protocol deviation through proactive high dose Thiamine prescription.

Improved diagnosis of WE Vs KP due to
- **Education effect** on medical staff.
- **Speciality unit admission** under Addiction medicine

POLICY IMPACTS
Alcohol related hospital presentations decreased in emergency presentations but remained consistent for chronic health impacts.

COMMUNITY IMPACTS
Community engagement through Indigenous Reference Group and health providers improved identification of alcohol related illness and consequent thiamine treatment.

Real world RCTs occur in complex and dynamic cultural, social and political landscapes that are key factors in understanding outcomes

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Conflict of Interest: Nil

Jennifer.Delima@nt.gov.au
C/O Alice Springs Hospital , PO Box 2234 Alice Springs NT 0871
Tel: 08 89517777