

FOpIT Trial <u>F</u>easibility of <u>Op</u>ioid <u>I</u>njection <u>T</u>rial

Implementation of time-limited parenteral hydromorphone in people with treatment-resistant injecting opioid use disorder: Safety, feasibility, acceptability and cost

Scottish Drugs Forum: Trends in Drug Use and Harms in Scotland.

Stirling, United Kingdom

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Anna McVinish, Clinical Nurse Consultant

Acknowledgement of Country





And another...







Background

- Australia has a *relatively* well-developed opioid agonist treatment (OAT) system but not all people respond to current treatment
- 5-15% people engaged in treatment continue injecting street opioids and experience severe harms (Lintzeris 2009)
- Approximately 10% clients who visited MSIC to use opioids in 2017 first registered with the service in 2001 – 2002, indicating prolonged injecting opioid use
- A MSIC client survey in 2017 found 43% respondents were currently on methadone and a further 35% had been on methadone previously

Lintzeris, N. (2009). Prescription of heroin for the management of heroin dependence. CNS drugs, 23(6), 463-476.



Injectable opioid treatment

- Supervised injectable Opioid Treatment (SIOT) is a second-line treatment option for people who continue to inject opioids despite access to OAT 1, 2
- Involves prescribing pharmaceutical heroin or hydromorphone for people who continue to inject despite access to treatment
- People may also receive supplementation with oral methadone to prevent withdrawal during inter-dosing intervals
- Injected opioids are more rewarding that oral OAT and can attract and hold people in structured treatment where methadone and buprenorphine have not been effective

Injectable opioid treatment is not a new idea!

 Bell, J., Belackova, V., & Lintzeris, N. (2018). Supervised Injectable Opioid Treatment (SIOT) for the Management of Opioid Dependence. *CNS drugs, online 21st August, 2018.* doi:DOI 10.1007/s40265-018-0962-y
Bell, J., van der Waal, R., & Strang, J. (2016). Supervised Injectable Heroin: A Clinical Perspective. *The Canadian Journal of Psychiatry, 62*(7), 451-456.

Therefore...



Integrating SIOT into existing public clinics represents a potentially more sustainable and accessible approach to managing people who have not responded to methadone or buprenorphine







- Most studies have investigated the effectiveness of SIOT vs methadone and have not tested the effectiveness of 'time limited' SIOT
- Studies have shown that most benefit from SIOT occurs in the first 6 months of treatment 1,2
- Data suggests that moderate-term SIOT and transfer to methadone may be a more effective use of resources than indefinite maintenance
- Participants in FOpIT are offered parenteral hydromorphone as an adjunct to methadone (or other agonist treatment) for up to 24 months followed by transfer to oral methadone or other agonist treatment

^{1.}Verthein, U., Bonorden-Kleij, K., Degkwitz, P., Dilg, C., Köhler, W. K., Passie, T., . . . Haasen, C. (2008). Long-term effects of heroin-assisted treatment in Germany. *Addiction*, *103*(6), 960-966.

^{2.} Oviedo-Joekes, E., Guh, D., Marchand, K., Marsh, D. C., Lock, K., Brissette, S., . . . Schechter, M. T. (2014). Differential long-term outcomes for voluntary and involuntary transition from injection to oral opioid maintenance treatment. *Substance Abuse Treatment, Prevention, and Policy, 9*(1), 23.

Partners



The project is a partnership between:

- Uniting NSW/ACT (MSIC)
- St Vincent's Hospital, Sydney
- University of NSW (UNSW)

Investigators

Prof Nadine Ezard Dr James Bell Dr Darren Roberts Prof Alison Ritter Prof Carla Treloar Dr Krista Siefried

Associate Investigators

Dr Marianne Jauncey Dr Vendula Belackova Prof Nick Lintzeris Prof Adrian Dunlop Prof John Strang Prof Wim van der Brink Prof Eugenia Oviedo-Joekes



Study design

- Single-site, uncontrolled, open-label implementation study recruiting 20-30, injecting, opioid-dependent people who have not found available treatments effective
- Participants are offered parenteral hydromorphone as an adjunct to oral methadone for up to 24 months
- Following transfer to oral methadone (or other agonist treatment), participants will be followed up for a further 3 months
- Participants are people who inject opioids not previously responding to conventional opioid agonist treatment
- The study will investigate the feasibility, safety, and cost of time-limited injectable hydromorphone treatment



Early data: recruitment

- 69 people expressed interest in the trial during the 6 month time frame
- 53 people underwent pre-screening with a trial nurse
- 22 participants screened by Medical Officer and deemed eligible
 - unfortunately unable to screen further participants due to limitations of space, staff and dosing times

Recruitment characteristics



- Age range 28 59 yrs (average 46 yrs age)
- 59% male, 36% female, 5% transgender
- 9% Aboriginal
- 36% identify as LGBTI
- 68% on current regular OAT at enrolment
 - (90% methadone, 5% Suboxone, 5% Buvidal)



Study procedures

- Participants self-administer (intravenous or intramuscular) parenteral hydromorphone (listed on Australian Register of Therapeutic Goods) twice-daily for 24-months under direct observation by nursing staff.
- Hydromorphone to commence at 10mg and increase incrementally each dose
- Dosage range **50-400 mg/day** (maximum 200 mg/dose)
- Co-administration of methadone (or other OAT) prior to any injection of hydromorphone
- Injection in **upper limbs only**
- Participants have only approximately 5 minutes to inject
- At 24 months all participants will transfer to standard OAT

Clinical flow





1. Dose confirmation of conventional OAT, administered within Rankin Court "dosing" hours.

2. Subsequent attendance for FOpIT side of the waiting roomshared space with Rankin Court.

3. Baseline observations and sedation assessment including self-report of recent use and sedation level.

4. Preparation of medication by RN 1 and RN 2.

5. RN 3 in injecting area observing self-administration and providing vein care.

6. 5-minutes post-dose observations and sedation assessment.

7. Move from injecting area to waiting room: aftercare, tea and a biscuit, opportunistic case management.

8. 15 mins post-dose - visual sedation assessment by nursing staff and clearance to leave.

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Challenges

- Fear/Stigma
- Covid
- Space; design and utility
- Co-location OTP
- Co-location acute care; tertiary referral + teaching hospital
- Clinical Emergency Response
- Emergent practice area:
 - Workforce
 - Education
- Hydromorphone







Innovation for OAT nursing workforce



 Dignity
PCC
TIC
Non-judgemental
Shame sensitivity
Treatment planning
Administration ritual
Research contribution
Harm reduction

Treatment expectations

OD risk Procurement and occupational stress Infection risk Unsterile equipment Criminal justice system Fear

Barriers navigating treat ment system

Rules and regs

Essentialist abstinence

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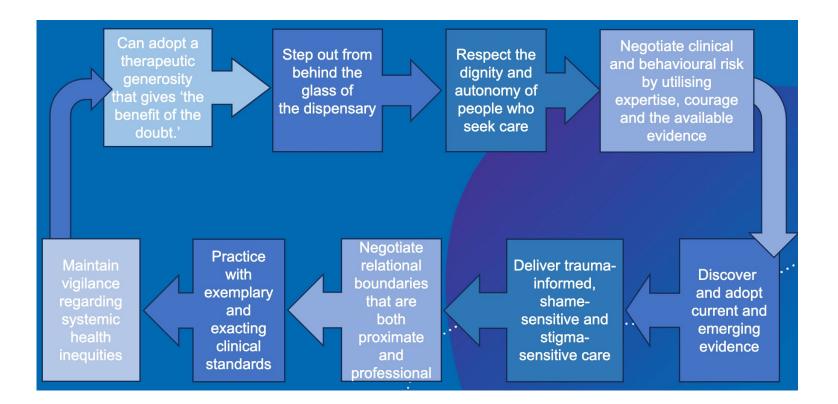


Fopportunities!





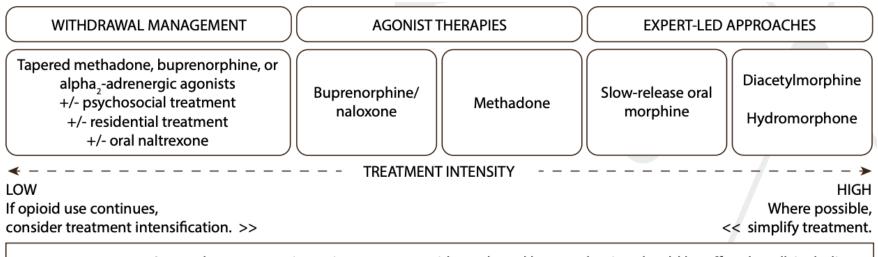
SIOT requires a workforce who:



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But what does it do?

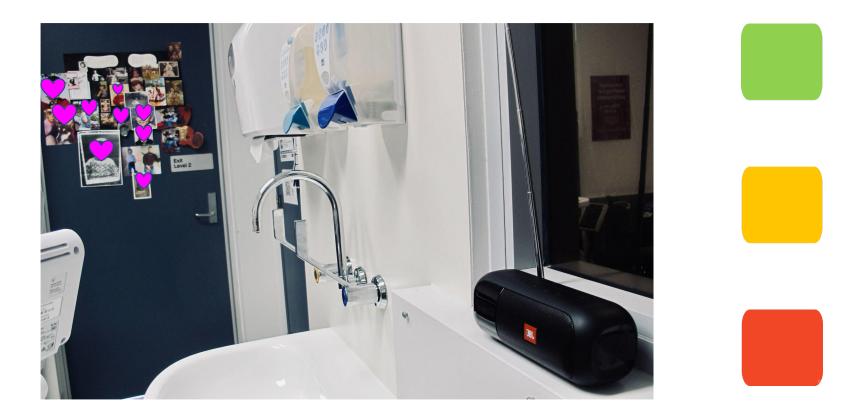


HARM REDUCTION	<u>Across</u> the treatment intensity spectrum, evidence-based harm reduction should be offered to all, including: • Education re: safer use of sterile syringes/needles and other applicable substance use equipment • Access to sterile syringes, needles, and other supplies • Access to Supervised Injection Sites (SIS) • Take-Home-Naloxone (THN) kits
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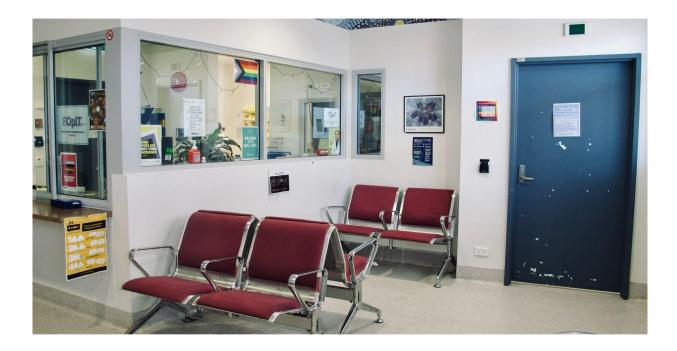
Maintaining amber







More than medication!



Summary



SIOT is a uniquely relational, nursing led treatment intervention that meaningfully expands Australia's current OAT delivery model.

And, it requires the synthesis of multiple care approaches and the delivery of adjunct therapies.

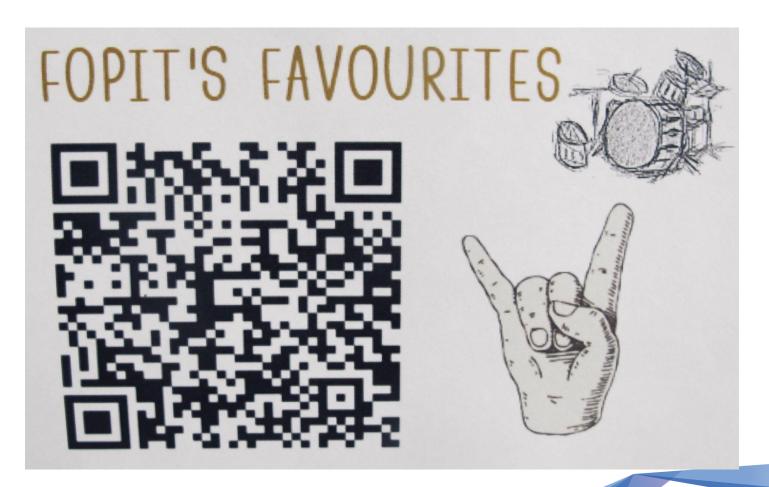
The Future







Questions?



anna.mcvinish@svha.org.au