Script in a Day (SCID) intervention for individuals injecting opioids: results from a mixed methods feasibility randomised control trial (RCT)

Professor Matthew Hickman, University of Bristol, UK
Acknowledgements

This is a summary of independent research funded by the National Institute for Health Research (NIHR)’s, Research for Patient Benefit (RfPB) programme (Reference Number PB-PG-0909-20007). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

• Collaborators:
  Dr Matthew Barber, General Practitioner (GP) & Principal Investigator (PI), National Health Service (NHS)
  Professor Matthew Hickman, University of Bristol (UoB)
  Dr Jenny Ingram, UoB and United Hospitals Bristol (UHB)
  Dr Rachel Ayres and Maggie Telfer, OBE, Bristol Drugs Project (BDP) a low threshold agency
  Dr Angela Beattie, Trial Manager (UoB)
Aims

• Potential effect: To investigate whether offering people who inject drugs (PWID) attending Bristol Drugs Project (BDP) immediate access to opioid substitution therapy (OST) via specialist primary care increased the number in OST at 3 months, compared to TAU (advice and case management).

• RCT Feasibility: Is it possible to recruit and follow-up PWID who have either dropped out of treatment or never accessed OST.
Background

• Systematic literature review –
  • Case finding increases uptake OST
  • Interventions (motivational interviewing, case management or mixed approaches)
    • But need to strengthen the evidence base as most studies originate from United States (Roberts et al. 2011)

• PPI at BDP wanted a more immediate and intense intervention
Methodology

- Un-blinded parallel-group feasibility RCT of same day access to OST (intervention group) compared with standard care with 3 month follow-up (control group)

- Participants - PWID presenting for needle exchange at Bristol Drugs Project and not in treatment for at least two weeks were invited to take part
SCID flow diagram of participants recruited into the trial

Assessed for Eligibility n=1371

Eligible but declined (n=211)
Not meeting inclusion criteria (n=1060)
Eligible and willing to participate (n=100)

Randomised (n=100)

Allocated to Control (n=51)
Received allocation (n=51)
Control (n=51)

Allocated to intervention (n=49)
Received allocation (n=43)
Did not receive allocated intervention (n=6); (already scripted n=3), did not arrive at GP n=2, no opioids detected in urine n=1

Completed Interview (n=44)
Uncontactable (n=6)
Moved away (n=1)
Medical records (n=47)

Completed interview (n=41)
Lost to follow-up:
Uncontactable (n=6) Moved away (n=1)
Deceased (n=1)
Medical records (n=48)

Analysed (47)
Excluded from analysis; (n=3) (unable to source information)

Analysed (49)
Excluded from analysis; (n=2) (unable to source information)
Outcome measures

Primary
• Still on script at 3 months following recruitment

Secondary
• The Treatment Outcomes Profile Measure (TOP) scale
• Health Related Quality of Life (HRQoL) measures:
  EQ-5D
  SF 12-v1
Follow-up at 3 months

<table>
<thead>
<tr>
<th></th>
<th>Intervention sample</th>
<th>Control sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Followed up at 3 months</td>
<td>83.7% (41/49)</td>
<td>86.3% (44/51)</td>
</tr>
<tr>
<td>Died during follow-up</td>
<td>2.0% (1/49)</td>
<td>0% (0/51)</td>
</tr>
<tr>
<td>Lost to follow up</td>
<td>14.3% (7/49)</td>
<td>13.7% (7/51)</td>
</tr>
<tr>
<td>Followed up at BDP</td>
<td>80.5% (33/41)</td>
<td>93.2% (41/44)</td>
</tr>
<tr>
<td>By phone</td>
<td>7.3% (3/41)</td>
<td>0% (0/44)</td>
</tr>
<tr>
<td>In prison</td>
<td>9.8% (4/41)</td>
<td>4.5% (2/44)</td>
</tr>
<tr>
<td>Via interpreter</td>
<td>2.4% (1/41)</td>
<td>2.3% (1/44)</td>
</tr>
</tbody>
</table>
### Outcome at 3 months – on a script

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-report</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On a script</td>
<td>58.5% (24/41)</td>
<td>54.5% (24/44)</td>
<td>0.83</td>
</tr>
<tr>
<td><strong>Medical, BDP &amp; Drug treatment agencies’ record search</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On a script</td>
<td>47.9% (23/48)</td>
<td>46.3% (19/41)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Composite result</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On a script</td>
<td>52.1% (25/48)</td>
<td>51.1% (24/47)</td>
<td>1.00</td>
</tr>
<tr>
<td>Substance</td>
<td>Mean (SD) baseline</td>
<td>Mean (SD) 3 months</td>
<td>Effect size for change at 3 months compared with baseline</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Alcohol</td>
<td>11.1 (11.5)</td>
<td>9.1 (11.4)</td>
<td>0.20 [-0.02, 0.42]</td>
</tr>
<tr>
<td>Opioids</td>
<td>23.5 (6.8)</td>
<td>9.9 (11.0)</td>
<td>1.15 [0.93, 1.36]</td>
</tr>
<tr>
<td>Crack</td>
<td>16.5 (10.6)</td>
<td>7.0 (9.4)</td>
<td>0.82 [0.60, 1.04]</td>
</tr>
</tbody>
</table>
# Health Related Quality of life (HRQoL) baseline to 3 months

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD) baseline</th>
<th>Mean (SD) 3 months</th>
<th>Effect size for change at 3 months compared with baseline</th>
<th>Effect size for difference between intervention and control at 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EQ-5D VAS (0 to 100 scale)</strong></td>
<td>49.8 (19.9)</td>
<td>60.0 (19.7)</td>
<td>0.45 [0.23, 0.67]</td>
<td>-0.06 (-0.50, -0.38)</td>
</tr>
<tr>
<td><strong>SF 12 physical HRQoL (0 to 100 scale)</strong></td>
<td>43.0 (23.4)</td>
<td>57.0 (25.3)</td>
<td>0.53 [0.32, 0.75]</td>
<td>0.08 [-0.36, 0.52]</td>
</tr>
<tr>
<td><strong>SF 12 mental HRQoL (0 to 100 scale)</strong></td>
<td>33.1 (21.2)</td>
<td>47.7 (25.3)</td>
<td>0.56 [0.35, 0.78]</td>
<td>0.43 [-0.01, 0.87]</td>
</tr>
</tbody>
</table>
Trial results

- No evidence of an intervention effect
- Opioid, alcohol and crack cocaine use decreased in both groups amongst those on OST
- Quality of Life gains for both intervention and control
- Trial feasible: Very high quality data
Qualitative Findings

• Completing baseline questionnaires seemed to be a motivating factor for the control group in seeking OST from their GP
  • Participants described discomfort after a period of reflection on reviewing their current drug use and health at baseline
  • Hawthorne Effect?
Conclusions

• Feasibility Trial was successful
  • PPI in intervention design; PWID recruited on time with high rates of follow-up
• But insufficient evidence on an intervention effect & full evaluation of SCID unwarranted
• Consider more intense management approaches incorporating regular neutral ‘health audit’ for Needle Syringe Programmes (NSP)…
Thank you for listening

E-mail: Matthew.Hickman@bristol.ac.uk