Rigorous Reporting of Stepped Wedge Cluster Randomised Controlled Trials: Development of a Flow Diagram Template

Dr Heather Gray
Weir CJ, Keerie C, McQueen J, Bain B, Brady M
Flightpath for Session

1. Overview of Stepped Wedge Cluster-RCTs
2. Reporting guidelines for Cluster RCTs
3. Overview of SOCLE 2 SW-CRT
4. Development of flow diagram for SW-CRTs
Stepped Wedge Cluster-RCT (SW-CRT)

- Relatively **new** type of RCT
- Modification of a crossover design
- Used in the **evaluation** of [health] service delivery interventions (Hemming et al, 2013; 2015)
- **Dramatic increase** in published SW-CRTs since 2010 (Beard et al, 2015; Grayling et al, 2017)
- **17 variations** on the typical SW-CRT design (Martin et al, 2016)
SW-CRT Design Features

- **Sequential roll-out** of an intervention
- Clusters are **sequentially randomised** to cross from the control to intervention arm (Martin et al, 2016)
- **All participants** receive intervention, but in a randomised order (Brown & Lilford, 2006)
- Significant **temporal trends** (Davey et al, 2015)
Randomised Controlled Trial

Recruitment

Site 1
- Intervention

Site 2
- Control
Cluster RCT

Recruitment

Site 1

Site 2

Intervention
Conventional Parallel Cluster Study vs. SW-CRT

(a) Parallel cluster study

Cluster
1
2
3
4
5
6

(b) Parallel cluster study with a baseline period

Cluster
1
2
3
4
5
6

(c) Stepped wedge study

Cluster
1
2
3
4
5
6

(d) Stepped wedge study including transition period

Cluster
1
2
3
4
5
6

Time

K Hemming et al. BMJ 2015;350:bmj.h391
SOCLE 2 Stepped Wedge

Cluster

<table>
<thead>
<tr>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
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<td>Usual Care</td>
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Month

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

Steps

Usual Care  Intervention  Enhanced Care

Time

Stroke Oral healthCare pLan Evaluation
SW-CRTs Rationale for Use

- Intervention predicted to do more good than harm (Hemmings et al., 2015)
- Logistical, practical or financial reasons
- Social acceptability (Beard et al., 2015)
  - Every cluster will eventually receive the intervention
- Study the effect of time on the effectiveness of an intervention (Mdege et al., 2011)
- Potentially efficient and pragmatic randomised study design (Hemmings et al., 2015)
SW-CRT Reporting

• Reporting of cluster RCTs is **complex**

• **Additional information required** to that of parallel group RCTs (Campbell et al, 2004)

• **Limitations in quality** of their reporting (Martin et al, 2016; Grayling et al, 2017)
  - Median number of CONSORT items reported across 60 SW-RCTs = **5 out of 9** (IQR 2–6)
  - 77% of studies reported schematic representation of design
Consolidated Standards of Reporting Trials (CONSORT)

- **Upsurge** in number of reporting standards for trials
- **CONSORT Guidelines** are intended to improve the reporting of RCTs
- Requirement for trial reports in many *journals*
- Original **CONSORT Statement** includes checklist and flow diagram (Schultz et al, 2010)
- **CONSORT Flow diagram**
  - Enrolment, intervention allocation, follow-up, and data analysis
CONSORT Flow Diagram for RCTs

**Enrollment**

Assessed for eligibility (n=)

- Excluded (n=)
  - Not meeting inclusion criteria (n=)
  - Declined to participate (n=)
  - Other reasons (n=)

**Randomized (n=)**

**Allocation**

Allocated to intervention (n=)
- Received allocated intervention (n=)
- Did not receive allocated intervention (give reasons) (n=)

Allocated to intervention (n=)
- Received allocated intervention (n=)
- Did not receive allocated intervention (give reasons) (n=)

**Follow-Up**

Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)

Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)

**Analysis**

Analysed (n=)
- Excluded from analysis (give reasons) (n=)

Analysed (n=)
- Excluded from analysis (give reasons) (n=)
CONSORT Extension

- Original flow diagram **insufficient for Cluster-RCTs**
- **Extended** CONSORT statement published (Campbell et al, 2004; 2012)
  - Includes the flow of both **clusters and individuals**
  - Not tailored for SW-CRTs
- New extension for SW-CRTs currently in development (Hemmings et al, 2014; 2016)
CONSORT Flow Diagram Cluster RCTs

- Assessed for eligibility (n=No of clusters)
  - Excluded (n=No of clusters):
    - Not meeting inclusion criteria (n=No of clusters)
    - Declined to participate (n=No of clusters)
    - Other reasons (n=No of clusters)

- Randomised (n=No of clusters)

- Allocation
  - Allocated to intervention (n=No of clusters):
    - Received allocated intervention (n=No of clusters, average cluster size, variance of cluster sizes)
    - Did not receive allocated intervention, give reasons (n=No of clusters, average cluster size, variance of cluster sizes)

- Follow-up
  - Lost to follow-up, give reasons (n=No of clusters, average cluster size, variance of cluster sizes)
  - Discontinued intervention, give reasons (n=No of clusters, average cluster size, variance of cluster sizes)

- Analysis
  - Analysed (n=No of clusters, average cluster size, variance of cluster sizes)
  - Excluded from analysis, give reasons (n=No of clusters, average cluster size, variance of cluster sizes)

Campbell et al, BMJ 2012; 345:e5661
CONSORT Flow Diagram Cluster RCTs

- Exact form and content **should vary** in relation to the specific features of a trial
- Type of diagram should depend on the **type of analysis** (Campbell et al, 2012)
- Different approaches to analysis require information at different levels of the clustered design
Stroke Oral healthCare pLan Evaluation (SOCLE): Phase II Stepped-Wedge Cluster Randomised Controlled Trial

Trial Registration: NCT01954212

Protocol

Clinical and cost effectiveness of enhanced oral healthcare in stroke care settings (SOCLE II): A pilot, stepped wedge, cluster randomized, controlled trial protocol

Marian C. Brady¹*, David Stott², Christopher J. Weir³,⁴, Campbell Chalmers⁵, Petrina Sweeney⁶, Cam Donaldson⁷, John Barr⁸, Marion Barr⁸, Alex Pollock¹, Sheena McGowan¹, Naomi Bowers¹, and Peter Langhorne²

Rationale Stroke-associated pneumonia, a leading cause of hospital-acquired infection after stroke, affects a fifth of stroke survivors annually. Associated with increased risk of death and poorer rehabilitation outcomes, research suggests a possible relationship between stroke-associated pneumonia and patients' oral health.

Discussion As one of the first stepped wedge, cluster random-
Research Questions (Phase II)

1. Can we determine pneumonia event rates across several sites and distribution over time post stroke onset?

2. Can we establish the association between dental and denture plaque and Stroke Associated Pneumonia?

3. Are SOCLE intervention and data collection processes viable across sites?

4. Can we refine our sample size calculations and estimates of recruitment and retention?
Outcomes Measures

- Patients
  - Pneumonia
  - Plaque

- Staff
  - Knowledge and attitudes
  - OHC assessments
  - OHC plans

- Services
  - Specialist referrals
  - Access to equipment/products

- Healthcare Costs
  - Staff
  - Training
  - Equipment/Products

(MRC, 2006)
Participants: Patients

- All ward admissions
- All ages, dentition profiles, and admissions
  - Including non-stroke
- Inclusive of people with communication problems (such as aphasia)
- Inclusive of people with incapacity
- No Exclusion Criteria
Participants: Staff

- Registered nurses,
- Nursing assistants,
- Nursing students
- Regular bank staff
- All shifts, full and part-time
- **No Exclusion Criteria**
Participants: Sites

Included
• Stroke rehabilitation wards within hospitals

Excluded
• Acute or hyper-acute stroke wards
SOCLE II - Stroke Oral healthCare pLan Evaluation

SOCLE II is a pilot trial of an enhanced oral health care service provision versus usual care. SOCLE II aims to evaluate the feasibility of a full trial of the clinical and cost effectiveness of a complex OHC service versus usual care for people in stroke care settings.

To learn more about the SOCLE II project please read the About Us page.

Volunteer Instructions

1. Log-in to access the restricted training materials.
2. Work through all 7 sections.
3. The estimated completion time is approximately 1.5 hours.
4. You can take a break at anytime and resume progress later.
5. When finished, please log-out.

Start
Take Home Messages

• SW-CRT suited this pragmatic trial of a complex intervention within a stroke care setting
• Stepped wedge design was feasible
• Start with the end in mind – reporting standards
• SOCLE 2 CONSORT flow diagram has the capacity to adjust to a variety of parameters
• Plans for OHC training to be available via the Stroke Training and Awareness Resources (STARS) website
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