Development of a Flow Diagram Template for Stepped Wedge Cluster Randomised Trials

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Outline

- Background
- Practical example
- The flow diagram template
- What have we learnt?
Background

Flow diagrams are central to the reporting of clinical trials.

Gaps exist in current reporting guidelines for SW-CRTs.

Particular design features need to be incorporated
Added level of complexity
Challenge

To report the flow of a stepped-wedge cluster randomised trial (SW-CRT).

Clear
Unambiguous
Tailored
Compliant with guidelines
SW-CRTs – Reporting quality

Systematic review  (Grayling et al, 2017)

• Increase in number of published SW-CRTs
• Variations in quality of reporting

https://doi.org/10.1186/s13063-017-1783-0
Current CONSORT Guidelines
Flow Diagram for RCTs

Demonstrates participant flow

Flow Diagram for Cluster RCTs

Demonstrates cluster and participant flow
Common Ground

Enrolment → Allocation → Follow-up → Analysis
Extending the guidelines - a practical example
Stroke Oral healthCare pLan Evaluation (SOCLE):
Phase II Stepped-Wedge Cluster Randomised Controlled Trial


Trial Registration: NCT01954212
Study setting

Design
Pilot study
Multi-centre - stroke care (n = 4)

Aims
Feasibility of a full scale trial
Standard oral care vs. complex intervention

Primary outcome
Patients – incidence of pneumonia

Does keeping your mouth and teeth clean avoid pneumonia?
Outcome Measures

**Patients**
- n = 325
  - Pneumonia
  - Plaque

**Staff**
- n = 112
  - Knowledge and attitudes
  - OHC assessments
  - OHC plans

**Services**
- Specialist referrals
- Access to equipment/products

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**Specialist OHC**

**Services**

**Outcome Measures**

**Materials and Methods**

**Analysis**

**Discussion**
SOCLE II Stepped Wedge Design

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**Usual Care**

**Intervention**

**Enhanced Care**

13 months of outcome data per site
Participant Flow Diagram

Sites approached: N=5
Declined: N=1

Site 1: PATIENTS
Admitted n=748
Screened n=400
Consented n=87

Site 2: PATIENTS
Admitted n=712
Screened n=401
Consented n=75

Site 3: PATIENTS
Admitted n=630
Screened n=563
Consented n=84

Site 4: PATIENTS
Admitted n=214
Screened n=144

4 sites

Analysis:
Usual Care
Patients n=135
Staff n=108

Intervention
Patients n=56
Staff n=74

Enhanced Care
Patients n=147
Staff n=83
Analysis totals

Usual Care

Intervention

Enhanced Care
Participant Flow Diagram

Site flow – in detail
Site 1 - Patients

- Screened: 440
- Consented: 87

Differences between phases

- Usual Care: 35
- Intervention: 15
- Enhanced Care: 40
Site 1 - Staff

Consented 26

Differences between phases

Usual Care
- K&A Q #1 25
- K&A Q #2 23
- K&A Q #3 21

Intervention
- K&A Q #4 22

Enhanced Care
- K&A Q #4 22
Staff Participant Flow Diagram
Participant Flow Diagram

Sites approached N=5
Declined N=1

Site 1
PATIENTS
Admitted n=748
Screened n=400
Consented n=353

STAFF
Employed n=28

Site 2
PATIENTS
Admitted n=712
Screened n=401
[Declined n=2]

STAFF
Employed n=36

Site 3
PATIENTS
Admitted n=639
Screened n=401

STAFF
Employed n=35

Site 4
PATIENTS
Admitted n=214
Screened n=401

STAFF
Employed n=24

Analysis

Follow-up
Analysis

Enrolment
Allocation
Follow-up
Analysis

Enrolment
Allocation

Usual Care
Patients n=135
Staff n=108

Intervention
Patients n=56
Staff n=74

Enhanced Care
Patients n=147
Staff n=83

Analysis
What have we learned?

Begin with the end in mind

- Ease of understanding
- Small number of sites
- Tailored
- Adaptable

?  
- Large number of sites
- More complex designs
- Standardisation

CONSORT  
TRANSPARENT REPORTING of TRIALS