Single Case Experimental Design

A bridge between Science and Practice? Feasibility Study 1.

Authors and Affiliations:
Peter Tucker[1],[2], Rebecca Ashton[1], Jennifer Limond[3], Sophie Gosling[1], Katie Byard[1], Howard Fine & Jonathan Reed[1].
Recolo UK Ltd[1], University of Bath UK[2], University of Exeter UK[3]

BACKGROUND:

There is a need for good quality evidence in paediatric neurorehabilitation. Single-Case Experimental Designs (SCEDs) are ideal for reporting behavioural interventions due to their flexibility (Tate et al. 2008). Being N-of-1 trials, SCED studies can be considered as Level 1 evidence for treatment benefit (OCEBM, 2016).

Standards for conducting and reporting SCED studies have improved recently (Evans et al. 2014). Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE) is a reporting guideline for SCEDs. This will be a helpful guide to build the evidence base with robust studies reflecting real clinical practice.

Recolo UK Ltd is a provider of community based paediatric neuropsychological rehabilitation for children and young people. The rehabilitation is litigation funded.

OBJECTIVE:

To test the feasibility of presenting routine neuropsychological rehabilitation practice as Level 1 evidence.

GOAL:

To run a pilot case with baseline, intervention and write up. The latter to include data analysis and learning points for the organisation.

METHOD:

A Single Case Experimental Design (SCED) in a service development context.

A system has been developed to produce routine rehabilitation within Single Case Experimental Designs. This involves a) recruitment, consent and design planning; b) intervention delivery within normal parameters of the rehabilitation; c) collection of additional activity data; d) write up and independent evaluation of report.

Ethics approval for this project was granted by the Psychology Department University of Bath.

A) RECRUITMENT, CONSENT & DESIGN

Participant: 10-year-old boy, cerebral palsy, fatigue, epilepsy, average IQ, visual, attention and memory impairment. Attainment two years below chronological age.

Context: lives at family home, attends mainstream school, normal curriculum, physical rehab 1- hour period per school day in a standing frame.

Goal setting: improvement of child's engagement in learning tasks a key priority.

Hypothesis: change in physical demands (timetable; standing practice) will help him engage better. This was collaboratively decided with family, child and MDT.

Dependent variable: task disengagement rating (independently by child, by adult). Adult ratings by TA, parents, teacher. Inter rater reliability of rating improved by training with use of video. Correlation between child and adult ratings of engagement r=.741 p<.01 (2-tailed). A low number represented high engagement. Simplified to a single rating time point at 3pm each day, i.e. when most disengaged. (See Figure 1.)

Figure 1. Disengagement rating key

1 **Completely engaged, trying really hard**
2 **Engaged, doing the activity most of the time**
3 **Interested and having a go**
4 **Dipping in and out of engagement**
5 **Reluctantly engaging**
6 **Avoiding the activity**
7 **Actively refusing the activity**

Secondary dependent variable: fatigue rating (child, adult).

B) INTERVENTION

Delivered within the normal parameters of the litigation funded rehabilitation.

Design: Initially - withdrawal reversal (ABAB) of lesson schedule (but prematurely implemented). Subsequently - withdrawal reversal (ABA) of child using standing frame in afternoon (A) and alternating afternoon and morning (B).

C) ASSOCIATE ACTIVITY DATA

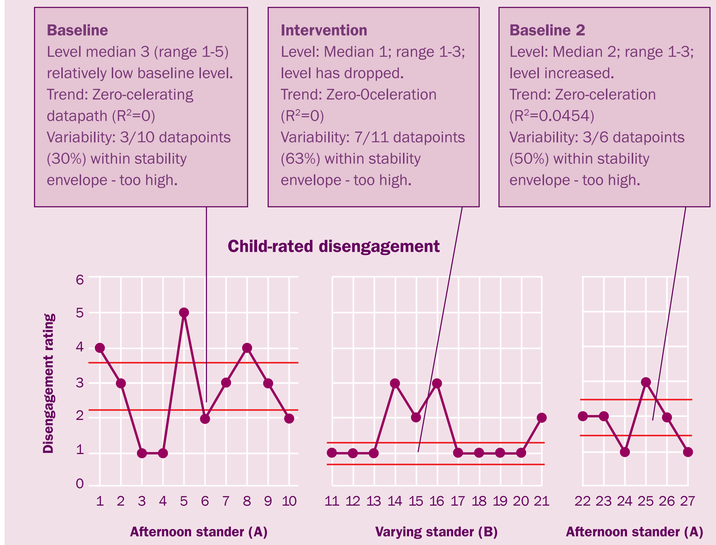
Total hours of additional Associate time beyond normal clinical practice: 32.25

D) WRITE UP: CLINICAL PRACTICE REPORT WITH RECOMMENDATIONS

Original plan to write up work for scrutiny by independent scrutineers against Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE).

Baseline (A) data collected, but timetable rescheduling occurred prematurely and without rating. Intervention then reconsidered with standing frame schedule as the independent variable. Intervention (B) was to distribute this activity differently. This occurred for 11 sessions. Returned to baseline (A) for 6 sessions. Three conditions therefore completed providing only two potential demonstrations of effect (A⟶B, B⟶A).

Figure 2: Data Analysis of Child-Rated Disengagement



**Red lines denote 'Stability Envelope'– a measure of variability: when approx. 80% of values are within +/-25% of the median value in each condition.*

Visual data analysis of the resulting data following Ledford et al. (2017):

At first sight there appears to be an overall reduction in disengagement across conditions. However further visual analysis revealed:

Level. There is improvement in the child's engagement over time. Reducing A⟶B (median 3 to 1), then increasing B⟶A (median 1 to 2).

Trend of zero-celeration, suggesting within-condition stability.

Variability is high across conditions.

Consistency. Data are neither consistent between the two baseline conditions or at changes in level (at A⟶B and at B⟶A).

Overlap. Presence of overlap between conditions. Insufficient condition changes to demonstrate effect.

Immediacy. No immediacy at both condition changes.

This analysis leads us to the conclusions:

1) **Within-condition variability** prevents determination about changes in level between conditions
2) **Inconsistency** and presence of **overlap** prevents any confidence in a functional relation

DISCUSSION:

Competing clinical and research priorities can be observed:

1. Clinical perspective: Enthusiasm of team about the intervention led to premature implementation. A secondary intervention developed and implemented. Overall, the family and teachers believed engagement had improved. Subsequently they decided to continue alternating stander as per B condition.
2. Research perspective: Unless we were certain intervention condition would result in large, immediate level changes and reduction in variability we should have collected more data at baseline before introduction of the intervention.

LIMITATIONS:

Research

- This was an opportunistic, not randomized or experimental design. Not appropriate for independent rating against Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE).
- Many possible confounding factors contribute to any observed change (e.g. self-rating = self-monitoring). Design control weakened by premature timetable rescheduling.

Clinical

- Research design changes what associate does clinically.
- Much time taken up on wide ranging data collection in early stages.
- Perceived control of the design over client centredness.
- Communication difficulties between practitioner, team and family.

Both

- Lack of clarity in early stages about goal, hypothesis, design and target variable.
- Risks to both clinical and research priorities.
- More time and cost than normal clinical practice.
- Complex system: child, school, family, rehab team, associate, research supervisor, research lead, clinical lead requiring careful management.

LEARNING POINTS:

- This process has led to several learning points from both research and clinical perspectives to take forward into future SCED projects.

OVERALL CONCLUSION:

More evidence needed to decide if it is feasible to present routine practice as level 1 evidence. Reflecting on what we have learned from this case, we continue to plan and run SCEDs in our service to build this evidence.

References:

Tate, R.L., McDonald, S., Perdices, M., Togher, L., Schultz, R., & Savage, S. (2008). Rating the methodological quality of single subject designs and n-of-1 trials: Introducing the Single-Case Experimental Design (SCED) Scale. *Neuropsychological Rehabilitation*, 18, 365-401.

Evans, J.J., Gast, D.L., Perdices, M. & Manolov, R. (2014). Single case experimental designs: introduction to a special issue of Neuropsychological Rehabilitation. *Neuropsychological Rehabilitation*, 24 (3-4), 305-14.

Ledford, J.R., Lane, J.D. & Severini, K.E. (2017). Systematic use of visual analysis for assessing outcomes in single case design studies. *Brain Impairment*, 19, (1), 4-17.

OCEBM Levels of Evidence Working Group. (2016). The Oxford Levels of Evidence 2. Oxford Centre for Evidence-Based Medicine. https://www.cebm.net/index.aspx?o=5653