## Kent Academic Repository

### Full text document (pdf)

#### Citation for published version

McGill, Peter and Vanono, Leah and Clover, Will and Smyth, Emmett and Cooper, Vivien and Hopkins, Lisa and Barratt, Nick and Joyce, Christopher J. and Henderson, Kate and Sekasi, Sheila and Davis, Susy and Deveau, Roy (2018) Reducing challenging behaviour of adults with intellectual disabilities in supported accommodation: A cluster randomized controlled trial of setting-wide

#### **DOI**

https://doi.org/10.1016/j.ridd.2018.04.020

#### Link to record in KAR

http://kar.kent.ac.uk/67062/

#### **Document Version**

Publisher pdf

#### Copyright & reuse

Content in the Kent Academic Repository is made available for research purposes. Unless otherwise stated all content is protected by copyright and in the absence of an open licence (eg Creative Commons), permissions for further reuse of content should be sought from the publisher, author or other copyright holder.

#### Versions of research

The version in the Kent Academic Repository may differ from the final published version.

Users are advised to check http://kar.kent.ac.uk for the status of the paper. Users should always cite the published version of record.

#### **Enquiries**

For any further enquiries regarding the licence status of this document, please contact: researchsupport@kent.ac.uk

If you believe this document infringes copyright then please contact the KAR admin team with the take-down information provided at http://kar.kent.ac.uk/contact.html





#### ARTICLE IN PRESS

Research in Developmental Disabilities xxx (xxxx) xxx-xxx



Contents lists available at ScienceDirect

#### Research in Developmental Disabilities

journal homepage: www.elsevier.com/locate/redevdis



# Reducing challenging behaviour of adults with intellectual disabilities in supported accommodation: A cluster randomized controlled trial of setting-wide positive behaviour support

Peter McGill<sup>a,\*</sup>, Leah Vanono<sup>a</sup>, Will Clover<sup>b</sup>, Emmett Smyth<sup>b</sup>, Vivien Cooper<sup>c</sup>, Lisa Hopkins<sup>d</sup>, Nick Barratt<sup>d</sup>, Christopher Joyce<sup>a</sup>, Kate Henderson<sup>e</sup>, Sheila Sekasi<sup>a</sup>, Susy Davis<sup>a</sup>, Roy Deveau<sup>a</sup>

#### ARTICLE INFO

Number of reviews completed is 2
This paper belongs to SI: Clustered/
Longitudinal

Keywords: Intellectual disability Adults Challenging behaviour Positive behaviour support Randomized controlled trial Supported accommodation

#### ABSTRACT

Background: Improving the quality of social care through the implementation of setting-wide positive behaviour support (SWPBS) may reduce and prevent challenging behaviour.

Method: Twenty-four supported accommodation settings were randomized to experimental or control conditions. Settings in both groups had access to individualized PBS either via the organisation's Behaviour Support Team or from external professionals. Additionally, within the experimental group, social care practice was reviewed and improvement programmes set going. Progress was supported through coaching managers and staff to enhance their performance and draw more effectively on existing resources, and through monthly monitoring over 8–11 months. Quality of support, quality of life and challenging behaviour were measured at baseline and after intervention with challenging behaviour being additionally measured at long-term follow-up 12–18 months later.

Results: Following intervention there were significant changes to social care practice and quality of support in the experimental group. Ratings of challenging behaviour declined significantly more in the experimental group and the difference between groups was maintained at follow-up. There was no significant difference between the groups in measurement of quality of life. Staff, family members and professionals evaluated the intervention and its outcomes positively.

Conclusions: Some challenging behaviour in social care settings may be prevented by SWPBS that

*Conclusions:* Some challenging behaviour in social care settings may be prevented by SWPBS that improves the quality of support provided to individuals.

#### 1. Introduction

Challenging behaviour remains a significant problem in supported accommodation settings for people with intellectual disabilities (cf. Department of Health, 2007). Almost half of residential services use restrictive responses such as physical intervention (Deveau & McGill, 2009). Challenging behaviour is associated with placement breakdown (Phillips & Rose, 2010) and the costly

https://doi.org/10.1016/j.ridd.2018.04.020

Received 3 November 2017; Received in revised form 15 March 2018; Accepted 23 April 2018 0891-4222/ © 2018 Published by Elsevier Ltd.

<sup>&</sup>lt;sup>a</sup> Tizard Centre, University of Kent, Canterbury, UK

<sup>&</sup>lt;sup>b</sup> University of Kent from Dimensions, UK

<sup>&</sup>lt;sup>c</sup> Challenging Behaviour Foundation, Chatham, UK

d Dimensions, UK

<sup>&</sup>lt;sup>e</sup> University of Kent from Kent and Medway NHS and Social Care Partnership Trust, UK

<sup>\*</sup> Corresponding author at: Tizard Centre, University of Kent, Cornwallis North East, Canterbury CT2 7NF, England, UK. E-mail address: P.McGill@kent.ac.uk (P. McGill).

Research in Developmental Disabilities xxx (xxxx) xxx-xxx

removal of individuals to more restrictive, out-of-area settings (Goodman, Nix, & Ritchie, 2006). Furthermore, it is associated with high rates of injury to care staff (National Task Force on Violence against Social Care Staff, 2001).

Generally, challenging behaviour is treated as an individual problem requiring intervention by psychologists, psychiatrists or other behaviour support professionals (Royal College of Psychiatrists, British Psychological Society, & Royal College of Speech and Language Therapists, 2007). But many such professionals now adopt *positive behaviour support* (PBS) (Carr et al., 2002), an approach inevitably leading to a focus on the context in which challenging behaviour occurs – "the central independent variable in PBS is systems change" (Carr, 2007, p.4). Such change is not easily obtained with regular reports of difficulties implementing the proposed treatments both in social care (Ager & O'May 2001) and educational settings (Bambara, Nonnemacher, & Kern, 2009). The difficult behaviour presented in schools has been recognised as requiring a broader approach, more focused on prevention (Sugai & Horner, 2002). The development of *school wide positive behaviour support* in the USA reflects this (Horner et al., 2009) but there has been little attention to the potential for a similar approach in social care.

A setting wide approach is consistent with theoretical developments in our understanding of challenging behaviour. Once seen as an almost inevitable concomitant of intellectual disability, it is now regarded as arising from the complex interaction of biological, developmental and environmental factors (Langthorne, McGill, & O'Reilly, 2007). In particular, it has become clear that certain characteristics of the social environment (such as social deprivation and aversive stimulation) may underpin the motivation of challenging behaviour (McGill, 1999). Altering such "motivating operations" (Michael, 2007; Simó-Pinatella et al., 2013) then becomes a theoretically viable approach to preventing or reducing the occurrence of challenging behaviour in those at increased biological risk (cf. Emerson & Einfeld, 2011).

Such an approach would need to focus on improving the quality of social care especially in those areas known (through the development of individualized PBS strategies) to be associated with challenging behaviour. These include, amongst others, opportunities for choice (e.g., Dyer, Dunlap, & Winterling, 1990), predictable environments (e.g., Flannery & Horner, 1994), positive social interactions (e.g., Magito-McLaughlin & Carr, 2005), more independent functioning (e.g., O'Reilly, Cannella, Sigafoos, & Lancioni, 2006) and personalised routines and activities (e.g., Brown, 1991). Such an approach has been endorsed by the NICE guidelines on challenging behaviour (Murphy, 2017; NICE Guidelines, 2015) in which the term "capable environment" is used to summarise the characteristics of support that may reduce the risk of challenging behaviour. There remains, however, very little evidence of the impact of such an environment. Most intervention trials have been of psychotropic medication with mixed results leading NICE to recommend that medication not be used as a first-line intervention for challenging behaviour. A small number of trials have shown that cognitive behaviour therapy (Vereenooghe & Langdon, 2013) and individualized PBS can be effective (Hassiotis et al., 2009). There is also evidence that training staff in PBS is associated with reductions in challenging behaviour (MacDonald & McGill, 2013). However, the impact of improving the quality of social care remains untested.

The current study set out to develop and evaluate an approach to improving the quality of social care in supported accommodation settings, drawing on work on quality improvement (e.g., LaVigna, Willis, Shaull, Abedi, & Sweitzer, 1994) and approaches to changing staff practice in residential settings (e.g., Mansell and Beadle-Brown, 2012). The primary hypothesis was that intervention would be associated with reductions in challenging behaviour. Secondary hypotheses were that intervention would lead to improved quality of support and a better quality of life. A parallel study, the results of which are reported separately, investigated the outcomes of the intervention for social care staff.

#### 2. Method

#### 2.1. Design

The study was carried out as a pragmatic, cluster randomised, controlled trial (RCT) (Hotopf, 2002). Intervention was implemented by a small team consisting of the Principal Investigator (PI), one full-time researcher and two part-time researchers. Two researchers implemented the intervention in each setting with one taking the lead and one a support role. Allocation of researchers to settings was geographically driven – the part-time researcher based in the North of England worked with settings in that region and the part-time researcher based in the South of England worked with settings in that region. The full-time researcher was involved in the intervention in all settings, either as lead or support. The PI supervised the intervention process through regular meetings and telephone conferences attended by the three researchers.

#### 2.2. Ethical and governance approvals

The study received ethical approval from the Social Care Research Ethics Committee (REC Reference 12/IEC08/0018) including for the participation of persons lacking capacity to consent. Governance applications were made to and agreed by 14 local authorities covering all the settings (control and experimental) that participated. Approval was also gained from the Association of Directors of Adult Social Services. Staff and intellectually disabled participants with capacity to consent received comprehensive, accessible information about the project and provided written consent. Intellectually disabled participants lacking capacity to consent participated (consistent with the *Mental Capacity Act*) through signed declarations from personal or nominated consultees.

#### 2.3. Settings and participants

The study ran from 2012 to 2016 in residential settings for 1-8 adults with intellectual disability. Social care in all settings was

Research in Developmental Disabilities xxx (xxxx) xxx-xxx

initially provided by *Dimensions*, a not-for-profit provider supporting 3500 people with intellectual disabilities and autism in England and Wales. Settings were geographically spread with two clusters in the South and North of England.

Dimensions was asked to identify 25–30 settings with an average of 4 adults with intellectual disabilities of whom (on average) two had a recent history of frequent and/or serious challenging behaviour. Additional inclusion criteria were that there were no significant changes planned (such as change of residents/tenants) and that residents/tenants and staff were likely to consent to participate. Thirty settings were identified and all contacted to confirm their meeting inclusion criteria and to begin seeking consent. Over approximately 6 months all settings were visited by researchers and the project discussed with the manager responsible. This led to the final identification of 24 settings where all residents/tenants and the great majority of staff had consented. Non-consenting staff participated in assessment and intervention procedures as part of their employment but did not complete measures or provide data.

#### 2.4. Intervention

Researchers, using positive behaviour support principles, sought to improve the quality of practice within experimental group settings using the following intervention process:

- 1. Managers and assistant managers of each setting attended a 3 h briefing session including presentations by *Dimensions'* Director of Specialist Development, the PI and the research staff involved in providing the intervention.
- 2. Two researchers were allocated to each setting as described above. All researchers engaged in intervention had a Master's degree in Applied Behaviour Analysis or Intellectual/Developmental Disabilities, and several years of experience in providing applied behaviour analysis/positive behaviour support. The PI was a registered clinical psychologist and board certified behaviour analyst with extensive experience.
- 3. Following an agreed timetable, researchers, in pairs, spent a week in each setting. The first two days involved observing practice, talking to staff and service users, and reviewing documentation. Researchers organised their findings into eight areas of social care - Activities and Skill Development, Health, Service Staff, Management, Relationships with Family and Others, Communication and Social Interaction, Wider Organisation, and Physical Environment. The eight areas were chosen based on research identifying their relationship with challenging behaviour. For example, substantial research shows the relationship between communication and challenging behaviour. When individuals understand what is going on and have effective ways of communicating their needs to the people supporting them, they are much less likely to display challenging behaviour. Similarly, and beyond the immediate context, aspects of the organisation may also impact on the occurrence of challenging behaviour. Organisational policies and practices, for example, should be informed by an understanding of challenging behaviour and ensure that frontline staff receive the support and leadership they need to work effectively. The specific areas identified represent an adaptation of previous attempts at evidenced taxonomies of those characteristics of mediators (Allen et al., 2013) and of environments (McGill, Bradshaw, Smyth, Hurman, & Roy, 2014) associated with less challenging behaviour. In each of the eight areas researchers identified, in discussion with the PI, the current picture, particular strengths, and areas where there was scope to support change within the setting. A comprehensive review of practice was presented to managers (including the manager's manager where possible). Having agreed an outline improvement programme and initial actions for all parties, researchers wrote a draft programme in which a small number of outcome standards (supported by several process and monitoring standards) were set out in each of the eight areas (cf. LaVigna et al., 1994).
- 4. A number of outcome standards were similar or the same in most/all settings or in at least some settings. All programmes also included standards idiosyncratic to one or two settings. The topics of standards are shown in Table 1.
- 5. Researchers returned to the setting as soon as possible after the initial week to present and discuss improvement plans.
- 6. Over the ensuing 8-11 months researchers engaged in a combination of the following activities tailored to each setting:
  - a. Monthly meetings with manager to review progress against the standards set. Progress was assessed using a traffic lights system with each "green" (standard fully achieved) being worth two points, "amber" (standard partly achieved) one point and "red" (standard not achieved) no points. Documentary evidence was required to score. Points were totalled so that a percentage figure could be calculated for each setting each month. The percentage represented the proportion of standards that had been achieved/partly achieved. Following each monthly meeting, total scores were graphed and sent to the manager so that everyone in the setting could see the progress being made.
  - b. Coaching staff and manager. In many settings staff received support to interact more effectively with the adults living there. This might, for example, be in the context of supporting participation in activity in ways that enabled engagement in the activity without provoking challenging behaviour.
  - c. Supporting the development of documentation. While all settings had extensive documentation it was not all functional. For example, there were limited activity schedules and staff frequently decided on the day what was going to happen. For some residents/tenants this was problematic since they could not predict or influence what was going to happen.
  - d. Staff and manager training. Where relevant to identified standards, more formal training was arranged. For example, an introductory session on autism was organised for a number of staff groups who supported individual(s) with autism but had little understanding of its influence on their behaviour.
  - e. Utilisation of existing *Dimensions* resources. Managers were encouraged to draw in support from other parts of the organisation. This included the organisation's behaviour support team, a coaching resource that enabled managers to receive support with difficult supervision issues and a resource that provided staff training specifically related to active support (Mansell & Beadle-Brown, 2012).

#### P. McGill et al.

**Table 1**Nature of standards set in experimental settings.

Area of social care	Standards commonly set	Standards idiosyncratic to one/two settings		
Activities and skill development	<ul> <li>Scheduling of varied activities that fit with individual routines and preferences</li> <li>Staff competence in active support of engagement in activity</li> <li>Organisation of materials for activities</li> <li>Development of sensory garden</li> </ul>	<ul> <li>Support of work opportunities/skills</li> <li>Supporting skills in time and money management</li> </ul>		
Service management	<ul> <li>Arrangement of holiday</li> <li>Provision of regular supervision and practice leadership of staff</li> <li>Full capacity staff team</li> </ul>	<ul> <li>Staff rotas</li> <li>Managerial expertise</li> <li>Induction of new staff</li> <li>Shift planning and organisation</li> <li>Wage payment systems</li> <li>Relationships with other agencies</li> <li>Staff team meetings</li> <li>Family contact and safeguarding</li> </ul>		
Physical environment	<ul> <li>Adaptations to meet individual needs</li> <li>Improvements to cleanliness/safety</li> <li>Access to functional space and personal equipment</li> </ul>	Garden amenities Transport availability Staff room refurbishment Community integration		
Relationships with family and others	<ul> <li>Maintaining regular, positive contact with family members</li> <li>Developing social relationships with friends and other non-family members</li> </ul>	Establishing family contact     Contact with neighbours     Spiritual guidance relating to bereavement		
Service staff	Increasing the knowledge and competence of staff regarding autism and/or challenging behaviour/positive behaviour support and/or active support Improving the knowledge and competence of staff in recording, interacting positively and providing consistent support, especially relating to decision-making and personal care	Improving staff team-working Improving staff understanding of confidentiality and keyworking responsibilities Staff support for personal appearance Staff understanding of appropriateness of different types of wheelchair		
Communication and social interaction	<ul> <li>Defining communication abilities of the people supported and how staff should provide support for communication and interaction</li> <li>Use of augmentative and assistive communication</li> <li>Increasing the amount of positive interaction and</li> </ul>	<ul> <li>Use of intensive interaction</li> <li>Use of visual activity schedules</li> <li>Use of social stories</li> <li>Provision of training for the people supported in greeting others and in negotiation</li> </ul>		
Health	communication by staff  Support of nutritional diets matched to individual preference and informed by specialist advice where necessary  Regular review of outstanding healthcare needs	<ul> <li>Understanding of medication side-effects</li> <li>Continence management and support</li> <li>Developing personal hygiene skills</li> <li>Supporting wearing of clothes appropriate to context</li> <li>Sleep hygiene</li> <li>Personal care routines</li> <li>A range of specific standards relating to single settings focussed on physiotherapy, visual impairment, offending, end of life plans, epilepsy, mobility, diagnosis and dental</li> </ul>		
Wider organisation	<ul> <li>Clarity and staff understanding of organisational policies especially those relating to touch, personal care and safeguarding</li> <li>Organisational support for complex staff and service management issues</li> </ul>	hygiene Staff knowledge and positive attitudes towards organisation Support for organisational change Organisational support for local community integration Ensuring smooth implementation of organisational IT processes A range of specific standards relating to single settings focussed on transport, audits and pets		

- f. Utilisation of local professional resources from outside *Dimensions*. Managers and staff were encouraged to seek input from local Community Intellectual Disability Teams (CIDTs) and other sources of potential support. For example, a referral was made to gain bereavement support following the death of one of the people who lived in a setting.
- g. Progress chasing. Researchers played a local leadership role in which they encouraged achievement of the standards using a variety of means. This included encouraging staff or manager to keep following something up or taking on specific tasks themselves.
- 7. Towards the end of the intervention, researchers reduced their input and sought to transfer outstanding activities to the manager or other *Dimensions* staff.

During the same period, control group settings received no input from researchers. They were, however, able to access additional input in the same way as before. This included making referrals within (e.g., to the behaviour support team or for coaching

 Table 2

 Standards set and achieved in experimental group settings.

Area of social care	Mean number of outcome standards set	Overall mean number of standards set (achieved)	Mean percentage achieved	Mean percentage achieved (commonly set standards)
Activities and skill development	2.6	22.5 (18.9)	84.0%	90%
Communication and social	2.3	14.9 (8.4)	56.4%	72%
interaction				
Health	3.9	23.3 (18.0)	77.3%	89%
Physical environment	3.0	19.5 (14.4)	73.8%	82%
Relationships with family and	2.4	15.8 (12.2)	77.2%	78%
others				
Service staff	4.2	18.5 (14.0)	75.7%	88%
Service management	4.0	18.3 (14.7)	80.3%	90%
Wider organisation	2.0	12.2 (8.3)	68.0%	77%
Total	24.4	145 (109)	75.2%	83.2%

assistance) and outside Dimensions (e.g., to the local CIDT).

#### 2.5. Intervention implementation

Within the experimental group monthly monitoring procedures allowed the collation of data on the standards set. The mean number of standards across settings was 145 (SD = 19.3, Range: 118–180). Table 2 shows the mean numbers of outcome and overall standards set and their achievement in each of the eight areas. Table 2 also shows the extent to which "shared" standards (those described above as having been set in some, most or all settings) were achieved. Standards were achieved at higher rates in certain areas of social care (Activities, Management, Staff, Health) and at lower rates in others (Physical environment, Relationships, Communication, Organisation). The correlation between overall standard and shared standard achievement was 0.85 suggesting that this pattern applied whether the standards were shared or more idiosyncratic. Shared standards did seem to be more likely to be achieved, an average of 83% vs the average of 75% for all standards.

Fig. 1 shows the percentage of standards achieved in each setting during the intervention. All settings started at 0% as standards were only included when clearly not achieved at initial assessment. While there was considerable overlap in standards set in different settings, the overall list of standards was idiographic to each setting and the percentage achieved cannot necessarily be meaningfully compared between settings. Overall average percentage achieved (median percentage in last data collection in each setting) was 80.1% (range: 29.7–92.3%). Service 7 was an outlier (see Fig. 1). This service was re-provided during the intervention for reasons unconnected with the intervention or challenging behaviour. As a result, the three adults were divided between two other settings supported by different providers. It was not meaningful to collect further data on the achievement of standards that did not necessarily apply to the new settings. While there was considerable variation (59.9–92.3%) in the remaining 10 settings, all made substantial and relatively steady progress towards achieving the standards set.

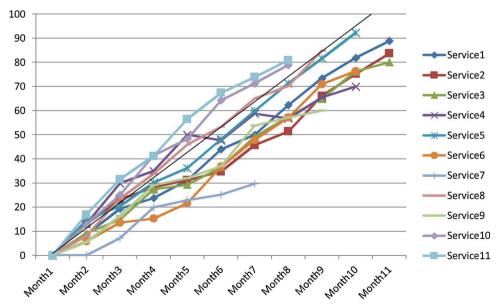


Fig. 1. Percentage of standards achieved over time in experimental group settings.

#### 2.6. Outcomes and other measures

The primary hypothesised outcome (reduction in challenging behaviour) was measured through the Aberrant Behavior Checklist-Community (ABC), a reliable and valid measure of the severity of challenging behaviour (Rojahn, Aman, Matson, & Mayville, 2003). Baseline questionnaires were completed prior to group allocation by staff who knew each adult well, typically their key worker. Subsequently, 3-6 months after the end of intervention, and 12-18 months after that, the same measure was completed. The secondary hypothesised outcomes (quality of life, and quality of staff support) were evaluated using non-participant observations made as close as possible to the period 4–6 PM in line with previous research (cf. Felce et al., 2000). Engagement in meaningful activity (as a measure of quality of life) was recorded using momentary time sampling during the 2-h period with observations made, by rotation, of all residents/tenants present. Engagement was defined as in the EMAC-R (Mansell & Beadle-Brown, 2005). Observers at baseline were research workers, one of whom had extensive experience in using the EMAC-R and provided training to the other. Observers after intervention were current or previous research workers with extensive experience in the use of EMAC-R. At the end of the 2-h period the observer completed the Active Support Measure (ASM) (Mansell & Elliott, 1996, revised 2005) which provided ratings of quality of staff support for activity, choice-making and other aspects of social care. Baseline data were gathered prior to randomisation of settings. Three-six months after the end of intervention, the same measures were carried out by observers with no previous involvement in the study and blind to group allocation. Inter-observer agreement was checked by having a second observer present during seven of the baseline and two of the post-intervention observations. Overall agreement about engagement occurred on 88.7% of observations. Exact agreement on ASM category scores was 79% with a weighted kappa of 0.72. Observers provided qualitative comments about each setting including their view on the setting's group membership, and their reasons for this conclusion.

Information on the characteristics of intellectually disabled participants was gathered using a shortened version of the *Individual Schedule* (IS) (Emerson et al., 1999) incorporating the *Short Adaptive Behavior Scale* (SABS) (Hatton et al., 2001). Questionnaires were completed prior to group allocation by staff who knew each individual well.

Following completion of the intervention, staff in experimental settings, family members of the people supported there and external professionals (e.g. CIDT members) with significant involvement completed one-page questionnaires on their experiences and overall evaluation of the intervention's impact. Questionnaires shared common items, expressed differently for different groups e.g. "Over the last year my relative's health has improved" (family version), "For the people we support the project has improved their health" (staff version), "The project has improved the health of the people supported" (external professional version). Additionally, staff questionnaires included four items relating to their own experiences of the project (e.g., "The project has improved the way I am supported by my manager"). All items were rated on a 5-point scale from "strongly disagree" that the intervention had a positive impact to "strongly agree".

#### 2.7. Sample size, randomization and blinding arrangements

In an RCT of the impact of behaviour support on challenging behaviour in individuals living in community settings, Hassiotis et al. (2009) estimated an effect size of 0.8 using the ABC. Effect size in the current study was therefore set at 0.8; with power set at 0.8 and p < 0.05 (one-tailed), 20 participants would be needed in each of the two groups.

Given the nature of the intervention, it would not have been possible to include participants from the same setting in both experimental and control groups. Accordingly, participants were grouped in clusters (where the cluster was the residential setting). With such an arrangement it was necessary to consider the within-cluster correlation. The magnitude of this effect is given by the formula:  $Deff = 1 + (m-1) \times ICC$  where Deff is the design effect, m is the average number of participants in each cluster and ICC is the intra-cluster correlation coefficient. The latter was estimated from unpublished data on challenging behaviour across 13 settings (clusters) of an adult social care provider collected by the PI as part of a service evaluation to be 0.096. Taking this as 0.1 and assuming an m of 2, the Deff is then 1.1 and 22 participants would be required in each group. On the basis of an average of 2 participants per placement this implied 11 settings per group. Settings were expected to also accommodate a similar number of individuals who did not display challenging behaviour. In total, therefore, the expected required sample was, in both experimental and control groups, 22 people who currently present challenging behaviour together with 22 people who did not currently present challenging behaviour. As noted below, the actual samples obtained approximated these requirements.

The 24 identified residential settings were allocated by the PI to experimental or control group using the computer programme MINIM (Evans, Royston, & Day, Undated). This method of allocation (minimisation, e.g., Treasure & MacRae, 1998) is particularly suitable for cluster trials containing a relatively small number of clusters since it ensures maximum similarity between groups in respect of variables that might influence outcome (cf. Turk et al., 2010). MINIM was set up to minimize differences between groups in respect of the following: geography (north vs south of England), number of staff in setting (above or below median), challenging behaviour (above or below median ABC score), number of adults without significant challenging behaviour (none vs one or more) adaptive behaviour (above or below median SABS score) and number of individuals with autism (0 vs 1 or more).

Given the nature of the trial, only limited blinding arrangements were possible. All baseline data were gathered prior to group allocation so both settings and researchers were blind at this stage. All settings were aware, however, at subsequent datapoints, whether they were in the experimental or control group. Gathering of data following intervention was facilitated by researchers aware of group allocation since they had been involved in delivering the intervention. The exception to this was in respect of the collection of non-participant observation and rating data following intervention. Observers had not previously been involved in the study and were blind to group allocation.

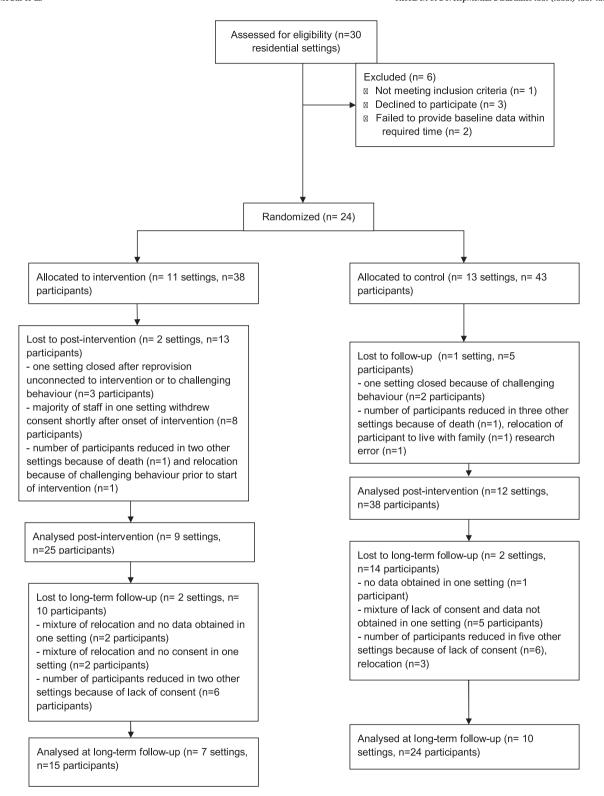


Fig. 2. CONSORT flow diagram.

**Table 3**Characteristics of experimental and control groups at baseline.

Characteristic	Experimental group (N = $11$ residential settings)	Control group (N = $13$ residential settings)	
Geographical location			
North of England	6	7	
South of England	5	6	
Average number of staff	9.8	12.9	
(range)	(5–18)	(5–30)	
Number of adults			
challenging behaviour	24	30	
no challenging behaviour	14	13	
Mean total score on ABC	43.5	57	
across settings for adults described as challenging (range)	(21-89)	(22–135)	
Mean total score on short	26.6	40.6	
ABS across settings (range)	(5–55)	(13–71.6)	
Number (percentage) of adults with autism diagnosis	13 (34%)	11(26%)	

#### 2.8. Analysis

All data analyses were conducted in IBM SPSS version 24. The period between baseline and post-intervention data collection was 12–18 months. During this time there were a number of changes to adult participation affecting data availability (see Fig. 2). Consequently, the experimental group was reduced from 11 to 9 settings, and the control group from 13 to 12 settings. Data are presented throughout, and analysis conducted, primarily at the setting level as that was the focus of the intervention and of randomisation. To investigate the degree to which setting level analysis reflected outcomes for individuals, a sensitivity analysis was conducted of changes in the primary outcome measure between baseline and post-intervention. This also allowed the impact of changes in the participants present at each datapoint to be investigated. Inferential analysis involved the comparison of group means in difference scores between baseline and post-intervention. Thus, a "per protocol" approach was used with no data imputation for those lost to follow-up. While an "intention to treat" approach would normally be regarded as the gold standard, the primary focus of this trial was to evaluate intervention efficacy.

Analysis of data at long-term follow-up (only possible for ABC scores) took a similar approach but is presented separately as there was more missing data and the study was originally planned with only baseline and post-intervention data points.

#### 3. Results

#### 3.1. Settings and participants

Eleven settings were allocated to the experimental group and 13 to the control group (see Fig. 2). Group composition, in terms of the variables used in allocation, is shown in Table 3. Group characteristics were compared using independent sample t-tests and, for categorical data, chi-square. None of the differences between groups were significant at p < 0.05, two-tailed.

Demographic information was gathered on all residents/tenants of the 24 residential settings (see Table 4).

#### 3.2. Outcomes after intervention

Average ABC scores for each setting are shown in Table 5. Setting average scores reduced in nine of nine experimental settings with the group mean reducing from 39.2 (range: 18.5–61) to 12.5 (range: 4–21). The control group mean reduced from 42.3 (range: 15.7–70) to 34.9 (range: 14–51.7) with seven of twelve settings reducing. The difference across time between groups was significant (t = 2.24, df = 19, p = .04, 2 tailed, Cohen's d = 1.00, 95% CIs -37.20 to -1.29).

Mean percentage ASM scores are also shown in Table 5. Mean scores increased in seven of nine experimental settings (remained the same in one and baseline data not gathered in the other) with the group mean increasing from 48.0 (range: 35.6–61) to 67.6 (range: 35.6–93.3). The control group mean reduced from 47.7 (range: 30.4–67.4) to 45.5 (range: 17.8–65.5) with five of twelve

**Table 4**Characteristics of adults with intellectual disabilities at baseline.

Characteristic	Total sample (N = 81)		Experimental group (N = 38)		Control group (N = 43)	
	N	%	N	%	N	%
Male	35	43.2	13	34.2	22	51.2
White Age	73 Mean = 39.7	90.1 Range: 19–84 years	37 Mean = 48.7	97.4 Range: 19–84 years	36 Mean = 31.7	83.7 Range: 19–60 years

Table 5

Average setting ABC total, ASM and Engagement percentage scores at baseline, after intervention and at follow-up (ABC only) (missing data in one setting at baseline because of client illness at scheduled observation time, see Fig. 2 re missing data at follow-up).

Group	Mean ABC at baseline	Mean ABC after intervention	Mean ABC at follow- up	Mean ASM percentage at baseline	Mean ASM percentage after intervention	Mean engagement at baseline	Mean engagement after intervention
Experimental	61.0	21.0	19.0	35.6	35.6	49.5	31.0
Settings	56.0	11.5	-	-	88.9		98.1
	35.0	8.0	7.5	80.0	84.4	78.5	99.0
	26.0	7.2	17.8	44.4	68.9	51.6	69.5
	23.1	11.3	32.5	40.4	42.2	17.0	60.0
	58.0	4.0	-	62.2	88.1	70.8	87.4
	51.5	19.5	24.5	50.0	93.3	78.3	69.8
	23.2	16.8	11.5	35.6	45.0	34.0	31.3
	18.5	13.0	16.0	35.6	83.3	12.3	67.4
Mean	39.2	12.5	18.4	48.0	67.6	49.0	68.2
Control Settings	30.7	40	26.5	30.4	36.2	85.4	43.1
	46.5	18.5	33.0	58.9	40.0	69.8	67.4
	15.7	45.5	15.5	51.8	65.5	33.3	64.8
	62.0	34.3	19.0	44.4	53.3	58.9	30.1
	45.2	51.7	48.4	50.4	57.0	54.9	65.6
	70.0	31.3	100.0	64.4	50.0	77.8	75.5
	48.6	46.0	51.0	46.7	34.4	45.8	73.1
	30.0	14.0	15.0	51.1	48.9	71.2	69.2
	23.6	37.2	38.0	31.1	25.8	5.2	18.2
	31.5	37.5	52.0	34.4	58.9	34.6	81.7
	63.0	38.0	_	47.8	17.8	46.6	31.7
	40.8	24.3	_	61.5	57.8	46.9	87.0
Mean	42.3	34.9	39.8	47.7	45.5	52.5	58.9

settings showing an increase. The difference across time between groups was significant (t = 2.88, df = 18, p = .01, 2 tailed, Cohen's d = 1.28, 95% CIs 5.92–37.88).

Mean percentage engagement in meaningful activity increased in experimental settings from 49% to 68.2% and, in control group settings, from 52.5% to 58.9%. The difference across time between groups was not significant (t = 0.75, df = 18, p = .46, 2 tailed, Cohen's d = 0.34, 95% CIs -16.37 to +34.44).

Post-intervention observers identified group membership of 19 of the 21 settings, correctly allocating control group settings in all instances and experimental group settings in seven out of nine instances. Kappa was 0.80. In noting their conclusions, observers made no comments suggesting blinding had been breached. All allocation reasons related to their observations of the quality of social care and/or its outcomes.

#### 3.3. Sensitivity analysis of changes in individual ABC scores

ABC scores reduced in 21 of 26 experimental participants with the group mean reducing from 34.5 (range: 3–92) to 11.8 (range: 0–26). The control group mean reduced from 43.2 (range: 0–135) to 36.8 (range: 0–102) with 17 of 38 individuals reducing. The difference across time between groups was non-significant (t = 1.85, df = 62, p = .07, 2 tailed, Cohen's d = 0.49, 95% CIs -33.89 to +1.24).

Post hoc analysis of individual scores suggested that higher ABC scores were recorded in smaller settings in the experimental group at baseline, resulting in higher setting average scores at baseline compared to individual scores since settings were weighted equally however many individuals were supported in each. There was no evidence that change in individual participants across time had affected results – post-intervention data was not collected on four participants, three in the control group (one death, one data collection error, one left setting) and one in the experimental group (one death) – a repeat of the analysis of differences across time produced almost identical results to those in Section 3.2.

#### 3.4. Outcomes at long-term follow-up

Setting average ABC scores at follow-up are shown in Table 5. Mean scores were 18.4 (range: 7.5-32.5) in the experimental group and 39.8 (range: 15-100) in the control group. Averages across the three time points are shown in Fig. 3. The difference from baseline to follow-up between groups was not significant (t=1.58, df=15, p=.13, 2 tailed, Cohen's d=0.85, 95% CIs -15.67-0.53) though the difference between groups at follow-up remained significant (t=2.13, df=15, p=.05, 2 tailed, Cohen's d=1.13, 95% CIs -42.88-0.01).

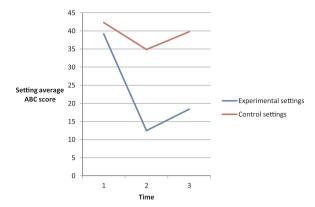


Fig. 3. Change in setting average ABC scores from baseline to follow-up and long-term follow-up.

#### 3.5. Social validity

Seventy-two staff (from all nine experimental settings) completed a questionnaire. Of the 787 individual ratings made, 68% recorded the intervention as having a positive impact, 25% as making no difference and 7% as not having a positive impact. Smaller numbers of family members (N = 8) and professionals (N = 12) completed questionnaires. 52% of family ratings were positive, 39% neutral and 9% negative. 77% of professional ratings were positive, 23% neutral and 0% negative.

As an additional indication of social validity, four experimental group services received awards.

#### 4. Discussion

The recent NICE guidance on challenging behaviour (Murphy, 2017) recognised the limitations surrounding previous research on challenging behaviour. In particular, there has been a shortage of research into the effectiveness of intervention employing the most robust designs (such as RCTs). As a result, our knowledge concerning intervention remains somewhat limited. The current study constitutes one of a very few RCTs on non-pharmacological treatment of the challenging behaviour of people with an intellectual disability. Its unique approach to "treatment" emphasised system-wide rather than individually-based intervention.

This approach proved a feasible way of working with most experimental group settings. There were two exceptions. In one setting, the intervention was interrupted by external "turbulence" with changed commissioning arrangements (independent of the research) requiring individuals to move to other settings supported by different care providers. In the other setting, the difficulties were related to the intervention which was, in a sense, a catalyst for change. Initial assessment identified a range of poor practice but its exposure alienated many staff working in the setting so that they withdrew their consent. It proved possible to continue delivering a form of the intervention, albeit under considerable difficulties and without adequate data collection. While implementation across other settings was variable, an average of 80% of the standards set were achieved and the percentage achieved steadily rose across the intervention period. Challenging behaviour (as measured by the primary outcome measure, ABC total scores) reduced by over 2/3rds in the experimental group. This reduction was significantly more than in the control group and constituted a large effect size, albeit sensitivity analysis suggested that the strength of the effect at individual participant level was rather less. Much of the reduction was maintained at follow-up. On the measure of quality of social care, experimental settings improved significantly more than control settings, again a large effect size. Quality of life for service users (as measured by observed engagement in meaningful activity) also improved more in experimental settings but the improvement was not significantly greater than in the control group. The intervention was greeted very positively by staff, families and professionals engaged with experimental settings.

There were a number of limitations to study design and implementation. A pragmatic RCT with usual care control is prone to the criticism that the intervention group received more "attention". With the design used all that can be concluded are the effects of the "attention" received rather than the intervention components that were instrumental in producing these effects (Woods & Russell, 2014). The earlier description of the intervention reveals the authors' assumptions about its critical components but further research would be necessary to endorse this. Similarly, it remains possible that control group staff suffered from "resentful demoralisation" (Woods & Russell, 2014, p.8) at not being included in the experimental group. However, on some of the measures employed, the control group improved from baseline, tending to argue against this possibility.

No information was collected on what happened in control group settings between baseline and post-intervention. Given their continued access to the organisation's behaviour support team, some are likely to have received significant input with respect to the challenging behaviour of individuals. In retrospect, monitoring the external input they received would have been useful. Attention should also be drawn to the routinely high staff turnover found in social care and its implications for longitudinal research. Inevitably, measures were often completed by different members of staff at different time points, introducing an additional source of variability. Future research might focus more on the use of measures that do not depend directly upon specific staff for their completion such as observation and routinely produced data such as incident reports. However, such measures also have their problems. Observation is costly and may not provide representative data, while incident reports are often of dubious reliability.

P McGill et al

Research in Developmental Disabilities xxx (xxxx) xxx-xxx

RCT designs remain relatively unusual in social care and the funding available for the current study did not allow the involvement of independent statisticians, methodologists and health economists that would be regarded as typical in healthcare research. This, inevitably, increases the possibility of bias and means that important variables (such as costs) were not measured. In particular, it should be noted that the same people were involved in both delivering the experimental condition and in the process of collecting and analysing data. As far as possible the risks of bias associated with this were reduced e.g. by employing observers blind to group membership and encouraging staff to return questionnaires in sealed envelopes. Nonetheless, it would clearly have been much better to have had sufficient independent research capacity to avoid such risks more completely.

A number of limitations also arose in the implementation of the study and should receive attention in future research. It would be useful to work with more than one social care provider to help test the generality of findings and to identify the characteristics of provider organisations required to support successful intervention. In the current study, the PI had a long-established relationship with the provider including at senior management level. It seems likely that this kind of relationship and support will enhance outcome but there is as yet no comparison on which to base such a judgement. The intervention was developed by the research team and has not yet been "manualized" in detail. This is clearly an essential step if attempts at replication and component analysis are to take place. In conducting the study it became clear that some aspects of measurement could have been improved. Four issues were identified. Firstly, the data produced through monthly monitoring of standard achievement was of unknown reliability and validity. Secondly, while direct observations are potentially very useful, the amount of time allocated to these in the current study may have been insufficient given the degree of variability that might be expected across relatively short periods. This may explain the failure to find significant differences between experimental and control group settings in engagement in meaningful activity. Thirdly, measurement of resident quality of life was limited and it would be useful to expand the range of measures used, perhaps exploring the use of ASCOT (Netten et al., 2010). Fourthly, it would be useful to measure the impact of the intervention on use of other services e.g., whether people are less likely to require psychiatric, psychological or other health input.

In summary, the findings of this study are promising and suggest that research on challenging behaviour should continue to investigate intervention in the system of supports surrounding individuals at risk of developing or continuing to display challenging behaviour. This implies that health and social care providers should consider the scope for directing some of their behaviour support resources at systemic, preventative intervention. In the case of *Dimensions*, they decided, having seen the results of the intervention, to implement a new model of support based on that used in experimental settings (see <a href="https://www.Dimensions-uk.org/initiative/activate/">https://www.Dimensions-uk.org/initiative/activate/</a>). The promising findings suggest that further studies should be carried out. Ideally, these studies would be larger, involve multiple providers, allow investigation of costs as well as outcomes and contribute to investigation of the factors potentially responsible for positive outcomes.

It might be argued that the findings of this study support a "social model" approach to challenging behaviour. That it is possible to substantially reduce challenging behaviour through interventions that are focussed more on the environmental context than the individual suggests an analogy with the prevention of disability (despite impairment) through the making of reasonable accommodations in the environment and wider society. This is both theoretically important, in extending our understanding of challenging behaviour, and practically important, in indicating steps we can take to its prevention.

#### Acknowledgements

The work reported here was funded by the NIHR School for Social Care Research (Grants T976/EM/KentGM2 and CO88/CM/UKJF-P71) and *Dimensions* Views expressed are the authors' and not necessarily those of the NIHR School for Social Care Research, Department of Health, NIHR, NHS or *Dimensions* (UK) Ltd. Athene Kok, Lisa Richardson, Gina Skourti and Hiromi Umizawa assisted with data collection. Dougal Hare provided free training in Autism. We are grateful for the support of an advisory group including Beverley Ashman, Eddy Hyde, Sarah Jane, Sue Kirkman, Lucinda Lindsay, Jo Poynter, Balwinder Sandhu and Naomi Sills. The project would not have been possible without the support and participation of the people with intellectual disabilities who lived in the residential settings involved, the staff supporting them and their managers. Other service provider staff (e.g. more senior managers and performance coaches) provided vital inputs. Many other professionals, family members and volunteers played a part in particular settings or in support of the achievement of particular standards. Thanks also to Kent Probation Services and ReMap who provided voluntary assistance in particular settings. The data gathered at long-term follow-up contributed to a dissertation submitted by Sheila Sekasi in partial fulfilment of the requirements of an MSc in Applied Behaviour Analysis at the University of Kent.

#### References

Ager, A., & O'May, F. (2001). Issues in the definition and implementation of best practice for staff delivery of interventions for challenging behaviour. *Journal of Intellectual and Developmental Disability*, 26(3), 243–256.

Allen, D., McGill, P., Hastings, R. P., Toogood, S., Baker, P., Gore, N. J., & Hughes, J. C. (2013). Implementing positive behavioural support: Changing social and organisational contexts. *International Journal of Positive Behavioural Support*, 3(2), 32–41.

Bambara, L. M., Nonnemacher, S., & Kern, L. (2009). Sustaining school-based individualized positive behavior support: Perceived barriers and enablers. *Journal of Positive Behavior Interventions*, 11(3), 161–176.

Brown, F. (1991). Creative daily scheduling: A nonintrusive approach to challenging behaviors in community residences. *Journal of the Association for Persons with Severe Handicaps*, 16(2), 75–84.

Carr, E. G. (2007). The expanding vision of positive behavior support: Research perspectives on happiness, helpfulness, hopefulness. *Journal of Positive Behavior Interventions*. 9(1), 3–14.

Carr, E. G., Dunlap, G., Horner, R. H., Koegel, R. L., Turnbull, A. P., Sailor, W., & Fox, L. (2002). Positive behavior support: Evolution of an applied science. *Journal of Positive Behavior Interventions*, 4(1), 4–16.

#### P McGill et al

- Department of Health (2007). Services for people with learning disabilities and challenging behaviour or mental health needs: (Chairman: Prof J.L. Mansell) (Revised ed.). London: Department of Health.
- Deveau, R., & McGill, P. (2009). Physical interventions for adults with intellectual disabilities: Survey of use, policy, training and monitoring. *Journal of Applied Research in Intellectual Disabilities*, 22, 145–151.
- Dyer, K., Dunlap, G., & Winterling, V. (1990). Effects of choice making on the serious problem behaviors of students with severe handicaps. *Journal of Applied Behavior Analysis*, 23, 515–524.
- Emerson, E., & Einfeld, S. L. (2011). Challenging behaviour. Cambridge: Cambridge University Press.
- Emerson, E., Robertson, J., Gregory, N., Hatton, C., Kessissoglou, S., Hallam, A., & Noonan Walsh, P. (1999). A comparative analysis of quality and costs in village communities, residential campuses and dispersed housing schemes. Manchester: Hester Adrian Research Centre, University of Manchester.
- Evans, S.M., Royston, P., Day, S., Undated. Minim: Allocation by minimisation in clinical trials, [Retrieved from https://www-users.york.ac.uk/~mb55/guide/minim.html.
- Felce, D., Lowe, K., Perry, J., Jones, E., Baxter, H., & Bowley, C. (2000). The quality of residential and day services for adults with intellectual disabilities in eight local authorities in England: Objective data gained in support of a social services inspectorate inspection. *Journal of Applied Research in Intellectual Disabilities*, 12(4), 273–293
- Flannery, K. B., & Horner, R. H. (1994). The relationship between predictability and problem behavior for students with severe disabilities. *Journal of Behavioral Education*, 4(2), 157–176.
- Goodman, N., Nix, J., & Ritchie, F. (2006). Out of area, out of sight: Review of out-of-area placement arrangements made by Social Services and Health for people with learning disabilities from the West Midlands. Tizard Learning Disability Review, 11(1), 35.
- Hassiotis, A., Robotham, D., Canagasabey, A., Romeo, R., Langridge, D., Blizard, R., & King, M. (2009). Randomised, single-blind, controlled trial of a specialist behaviour therapy team for challenging behaviour in adults with intellectual disabilities. *American Journal of Psychiatry*, 166, 1278–1285.
- Hatton, C., Emerson, E., Robertson, J., Gregory, N., Kessissoglou, S., Perry, J., & Hillery, J. (2001). The adaptive behavior scale-residential and community (part 1): Towards the development of a short form. Research in Developmental Disabilities, 22, 273–288.
- Horner, R. H., Sugai, G., Smolkowski, K., Eber, L., Nakasato, J., Todd, A. W., & Esperanza, J. (2009). A randomized, wait-list controlled effectiveness trial assessing school-wide positive behavior support in elementary schools. *Journal of Positive Behavior Interventions*, 11(3), 133–144.
- Hotopf, M. (2002). The pragmatic randomised controlled trial. Advances in Psychiatric Treatment, 8, 326-333.
- Langthorne, P., McGill, P., & O'Reilly, M. (2007). Incorporating motivation into the functional analysis of challenging behaviour: On the interactive and integrative potential of the motivating operation. *Behavior Modification*, 31(4), 466–487.
- LaVigna, G. W., Willis, T., Shaull, J., Abedi, M., & Sweitzer, M. (1994). The periodic service review: A total quality assurance system for human services and education. Baltimore: Paul H Brookes.
- MacDonald, A., & McGill, P. (2013). Outcomes of staff training in positive behaviour support: A systematic review. *Journal of Developmental and Physical Disabilities*, 25(1), 17–33.
- Magito-McLaughlin, D., & Carr, E. G. (2005). Quality of rapport as a setting event for problem behavior: Assessment and intervention. *Journal of Positive Behavior Interventions*, 7(2), 68–91.
- Mansell, J., & Beadle-Brown, J. (2005). Engagement in meaningful activity and relationships: An observational measure. Canterbury: Tizard Centre.
- Mansell, J., & Beadle-Brown, J. (2012). Active support: Enabling and empowering people with intellectual disabilities. London: Jessica Kingsley.
- Mansell, J., & Elliott, T. E. (1996). Active support measure. Canterbury: The Tizard Centre.
- McGill, P. (1999). Establishing operations: Implications for the assessment, treatment and prevention of problem behavior. *Journal of Applied Behavior Analysis*, 32(3), 393–418.
- McGill, P., Bradshaw, J., Smyth, G., Hurman, M., & Roy, A. (2014). Capable environments. Retrieved from https://www.kcl.ac.uk/sspp/policy-institute/scwru/news/2014/newsfolder/McGill-et-al-Capable-environments.pdf.
- Michael, J. (2007). Motivating operations. In J. O. Cooper, T. E. Heron, & W. L. Heward (Eds.). Applied behavior analysis (pp. 374–391). (2nd ed.). Upper Saddle River, NJ: Pearson Education.
- Murphy, G. (2017). The NICE guidelines on learning disabilities and behaviour that challenges. Tizard Learning Disability Review, 22(2), 71-81.
- NICE Guidelines [NG11] (2015). Challenging behaviour and learning disabilities: Prevention and interventions for people with learning disabilities whose behaviour challenges. https://www.nice.org.uk/guidance/ng11.
- National Task Force on Violence against Social Care Staff (2001). Report and national action planLondon: Department of Health.
- Netten, A., Forder, J., Beadle-Brown, J., Caiels, J., Malley, J., Smith, N., & Windle, K. (2010). ASCOT Adult social care outcomes toolkit. Personal Social Services

  Research Unit
- O'Reilly, M., Cannella, H., Sigafoos, J., & Lancioni, G. (2006). Communication and social skills interventionis. In J. K. Luiselli (Ed.). Antecedent assessment and intervention: Supporting children and adults with developmental disabilities in community settings (pp. 187–206). Baltimore: Paul H Brookes.
- Phillips, N., & Rose, J. (2010). Predicting placement breakdown: Individual and environmental factors associated with the success or failure of community residential placements for adults with intellectual disabilities. *Journal of Applied Research in Intellectual Disabilities, 23*(3), 201–213.
- Rojahn, J., Aman, M. G., Matson, J. L., & Mayville, E. (2003). The aberrant behavior checklist and the behavior problems inventory: Convergent and divergent validity. Research in Developmental Disabilities, 24(5), 391–404.
- Royal College of Psychiatrists (2007). British Psychological Society, & Royal College of Speech and Language Therapists. Challenging behaviour: A unified approach. London: Royal College of Psychiatrists.
- Simó-Pinatella, D., Font-Roura, J., Planella-Morató, J., McGill, P., Alomar-Kurz, E., & Giné, C. (2013). Types of motivating operations in interventions with problem behaviour: A systematic review. *Behavior Modification*, *37*(1), 3–38.
- Sugai, G., & Horner, R. H. (2002). The evolution of discipline practices: School-wide positive behavior supports. *Child and Family Behavior Therapy*, 24(1/2), 23–50.
- Treasure, T., & MacRae, K. D. (1998). Minimisation: The platinum standard for trials? *BMJ*, *317*(8 August), 362–363.

  Turk, V., Burchell, S., Burrha, S., Corney, R., Elliott, S., Kerry, S., & Painter, K. (2010). An evaluation of the implementation of hand held health records with adults with learning disabilities: A cluster randomized controlled trial. *Journal of Applied Research in Intellectual Disabilities*, *23*, 100–111.
- Vereenooghe, L., & Langdon, P. E. (2013). Psychological therapies for people with intellectual disabilities: A systematic review and meta-analysis. Research in Developmental Disabilities, 34(11), 4085–4102.
- Woods, B., & Russell, I. (2014). Randomisation and chance-based designs in social care research. London: NIHR School of Social Care Research.