Neuropsychological Rehabilitation, 2014
Vol. 24, Nos. 3–4, 365–381, http://dx.doi.org/10.1080/09602011.2014.915856

Single case methodology in neurobehavioural rehabilitation: Preliminary findings on biofeedback in the treatment of challenging behaviour

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(*Received 21 October 2013; accepted 13 April 2014*)

The use of single-case methodology (SCM) in brain injury rehabilitation is described and contrasted with other methodologies. SCM is optimal when attempting to meet highly individual presentations or to trial innovative solutions. Portable biofeedback is a potentially effective means of helping persons with brain injury to recognise and regulate emotional states. Emotional dysregulation, associated with disinhibition on tests of executive function, is hypothesised to underpin aggressive challenging behaviour and may be amenable to feedback on heart rate variability, a marker for stress. Two case studies of a novel biofeedback intervention, emWave2, to address aggression directed towards the self and towards others are presented. Data from two A-B designs were analysed using the non-overlap all pairs (NAP) statistical method. Clinical significance of outcome is reported in both cases but only Case 2 reached statistical significance. The discussion highlights limitations of the methodology. Results are discussed in relation to the device helping participants differentiate the physiological state associated with stress. The future application of wearable physiological sensing and feedback systems is explored.

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Our sincere thanks go to both participants for taking part in this trial and for giving valuable feedback. We are indebted to our rehabilitation support worker colleagues for carefully recording target behaviours and to Rebecca Goodfellow for data entry. Thanks to Giles Yeates for bringing the possibility of the intervention to our attention. We acknowledge Rumen Manolov for suggesting the statistical approach employed. We are grateful to Rollin McCraty for permission to use the graphic presented in Figure 1.

Keywords: Brain injury; Rehabilitation; Challenging behaviour; Heart rate variability; Biofeedback.

INTRODUCTION

Injury to the brain leads to a wide variety of problem presentations. Rather than brain injury conferring a diagnostic entity with treatment options, it leads to constellations of difficulties often requiring individualised treatments. This heterogeneity of presentation necessitates a person-centred approach to assess the effects of environments, medicines, psychological therapies, retraining programmes and assistive technologies on a person's behavioural presentation.

Neurobehavioural disability refers to the sequelae of brain injury in the areas of behavioural control and its impacts on functional abilities and interpersonal relationships (Alderman, Wood, & Williams, 2011). It refers to the changes in behaviour, secondary to emotional dysregulation, insensitivity and poor decision making which others find challenging to be around. Neurobehavioural disability has been implicated in difficulties maintaining social role (Wood, 2001) and social support (Willier, Flaherty, & Coallier, 2001). This article will place particular emphasis on behaviour which is challenging to persons in the service-users' environment. This has consistently been reported to be the most difficult aspect of adjustment to brain injury in a loved one (Bond, Brooks, & McKinlay, 1979) and a key factor in the fragility of relationships after brain injury (Gosling & Oddy, 1999).

The disruption of the ability to carry out various valorised functions (Malec & Lezak, 2003) necessitates rehabilitation to return the person to participation in a meaningful social life (Society for Research in Rehabilitation, 2012). Fundamental to this participation is the ability to regulate emotional state, deficits in which underpin both behaviour that is challenging to others as well as problems with higher-level cognition.

The evidence-based medicine (EBM) paradigm has moved us away from clinical experience, received wisdom or tradition as grounds for deciding on an intervention. The randomised control trial is considered the highest level of methodological quality in EMB efficacy research (e.g., Schulz, Altman, & Moher, 2010). In essence, this method involves recruiting a sample of sufficient power, randomly allocating to treatment or placebo control groups, blinding outcome assessment, and using parametric statistical approaches to discern differences in outcome which can then be attributed to the intervention. An effect size calculation can be used to quantify the strength of the effect of the intervention on the outcome variables. This, in turn, allows comparison between interventions (Cohen, 1988).

The double-blind placebo-controlled randomised trial is the best way to detect change attributable to a medicinal product in a sample of persons with the same presenting problem. However, where a person or persons (a) have an unknown or rare presentation; (b) exhibit a complex behavioural pattern rather than a single symptom or single diagnosis; (c) are not insightful to the existence of a problem; and (d) the intervention is not a medicinal product, then the RCT is not necessarily the most methodologically rigorous approach. Rarity of the presenting problem may lead to insufficient samples of recruits to randomise with sufficient power; withholding of treatment where the behaviour incurs risk may not be ethical; and recruits cannot be easily blinded to the interventions as delivered by persons (such as psychologists, occupational therapists, physiotherapists or speech and language therapists) or technologies. As such, we can neither adopt a one size fits all approach nor rely on population-specific randomised control trials to indicate interventions.

In rehabilitation settings there is a need to be both evidence based and address highly specific needs. We regularly are required to ascertain: (a) whether change in presentation can be attributed to an intervention; (b) whether an intervention is effective for the service user; and (c) whether this intervention might work for others with similar presentations. Single-case methodologies allow us to answer such questions.

This study will utilise measurement and feedback of heart rate variability, a physiological marker for the experience of negative emotional states such as stress and anxiety (Lehrer, 2007), depressed mood (Carney et al., 2001), and anger (Denson, Grisham, & Moulds, 2011). While disturbances of each of these emotional states are prevalent psychopathologies after brain injury, the relationship between lowered heart rate variability and anger (Denson et al., 2011) indicates the potential of heart rate biofeedback interventions to address agitation, irritability and interpersonal problems after brain injury.

Biofeedback technologies may be used to increase heart rate variability and thereby reduce arousal. Heart rate variability (HRV) is defined as the amount of fluctuation from the mean heart rate (Rechlin, Weis, Spitzer, & Kaschka, 1994) and represents the interaction between sympathetic and parasympathetic influences on the heart. Higher HRV is associated with better physical and mental health (Rechlin et al., 1994).

A small number of studies have suggested that biofeedback with instruction to engage in slow diaphragmatic breathing can increase HRV and reduce symptoms in patients with different disorders of the autonomic nervous system. Studies recruiting individuals with asthma, hypertension and heart disease have shown positive responses (Lehrer et al., 2003; McCraty, Atkinson, & Tomasino, 2003; Nolan, Kamatha, Floras, & Stanley, 2005). Furthermore, case studies have shown that HRV biofeedback may improve somatisation difficulties (Hassett et al., 2007) and depression (Karavidas et al., 2007).

The benefits of biofeedback for problems associated with brain injury are less clear. Tries (1990) found that myographic biofeedback could be used to increase awareness of bladder sensations and reduced incontinence. Guercio, Chittum, and McMorrow (1997) found that ataxia after brain injury was improved after biofeedback.

Kim et al. (2013) reported using HRV biofeedback in moderate to severe brain injury patients to explore whether HRV biofeedback improved emotional regulation and problem solving ability. Although they failed to find an association between improvement in behavioural and cognitive control and increase in HRV resonance, their result confirmed that an association does exist between an individual's performance and his or her emotional control.

Many psychological therapies are cognitively demanding and thus ineffective for people with severe brain injury and significant cognitive impairment. In contrast, biofeedback systems typically make minimal cognitive demands and so may be particularly suited to use with people with cognitive impairment. Increasing ability to identify bodily sensations associated with frustration or anger could act as an early warning signal to a possible behavioural outburst, thus helping to facilitate behavioural control.

This article will present two case studies examining the use of emWave2 in aiding the self-regulation of emotional problems and challenging behaviour following traumatic brain injury (TBI). EmWave2 is an HRV biofeedback system which is used to support slow diaphragmatic breathing and thereby increase HRV.

METHOD

Setting

The intervention took place in a specialised hospital for the rehabilitation of people with complex needs, including behaviour which challenges service provision, after brain injury. An interdisciplinary team provided intervention including psychiatric medication. Medications were kept constant during the period over which change is reported.

Materials

The Institute of HeartMath (https://www.heartmathstore.com/category/emWave2/) developed and marketed emWave2 as a biofeedback device. It measures and provides feedback on HRV via a light emitting diode (LED) display, emitted sounds or computer interface visualisation. It provides support for breath pacing using a moving LED display.

The device measures HRV via an earlobe sensor. This houses a photoplethysmograph comprising a light source, a light detector and a microprocessor. The light passed through the earlobe is absorbed by the haemoglobin in the pulsing blood, allowing detection of the phasic change in blood volume with each heartbeat. The device processes the signal from the sensor using an algorithm of HRV (explained below) to give feedback termed heart rate coherence. Positive feedback on high coherence is in the form of a green light on the device (as opposed to blue for medium coherence or red for low) and a pleasant high pitched tone sounds (as opposed to a medium or low tone in medium or low coherence). There are two versions available: desk top and portable. This study utilised the portable emWave2, meaning that the device did not need to be attached to a computer when in use.

The emWave2 device analyses the power spectrum of HRV to give feedback on coherence. The HRV wave is broken down into its frequency components corresponding to the different states of activity of the autonomic nervous system. Peaks in the very low frequency (VLF) of the spectrum correspond to sympathetic activity. Low frequency (LF) peaks reflect both sympathetic and parasympathetic activity. High frequency (HF) indicates parasympathetic or vagal activity.

Coherence is defined as a cluster of peaks in the low frequency range (circa 0.1 Hz). Coherence is differentiated from a relaxed state (characterised by peaks clustering in the HF range around 0.2 Hz). The state reflected by high coherence feedback has thus greater similarity to a meditative state (Murata et al., 2004).

The coherence score is calculated by first identifying the maximum peak in the 0.04–0.26 Hz (LF) range. The peak power is then determined by calculating the integral in a window 0.030 Hz wide, centred on the peak. The total power of the entire spectrum is then calculated. The coherence ratio is formulated as: Peak Power divided by (Total Power minus Peak Power) squared (see Figure 1). This method provides an accurate measure of coherence, allowing for the nonlinear nature of the HRV waveform over time.

Procedure

Participants were supervised in their use of emWave2 for 10–20 min per day, circa 10 a.m. Monday to Friday. Supervision (BON, GF) ensured that users were attending to the feedback from the device. The device was introduced as an experimental device which may have an effect on a person's resilience to stress. The authors were not licenced Heartmath trainers as this was not feasible at the time of the intervention. The authors are experienced in providing instruction within psychological treatment paradigms.

Participants were trained in how to reach a coherent state as per the emWave2 Owners Manual (Heartmath, 2011) The device users were

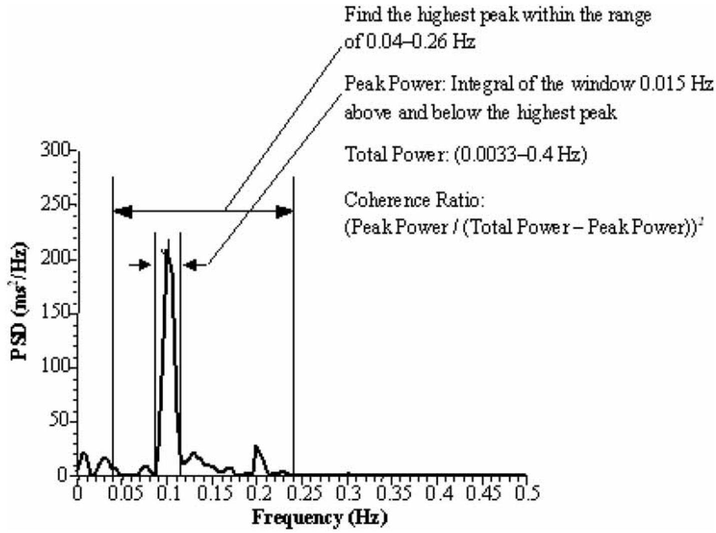

Figure 1. Calculating coherence from heart rate variability.

instructed to inhale and exhale as the lights of the pacer rise and fall, maintain an attentional focus in the region of the heart, and activate a memory or attitude of "appreciation".

Measures of challenging behaviour (OASMNR; Alderman, Knight, & Morgan, 1997) were kept routinely in the setting and thus the effect of the intervention on clinical variables of interest could be assessed empirically. It was not possible to blind participants or therapist as to phase. Behavioural data were collected by rehabilitation support workers who did not know that participants were receiving the intervention and were therefore blind to study phase.

Ethics

The intervention was deemed plausible due to the clinical presentations of the cases described. Service users gave informed consent to the trial. Publication of the case series was retrospectively approved by the institutional Research Ethics Committee.

Measures

Case 1. Self-injurious behaviour as measured by the OAS-MNR with weightings for severity of injury along a four point scale (Alderman et al., 1997). Alderman et al. (1997) demonstrated that this measure had good inter-rater reliability with weighted Kappa values in excess of .90.

Convergent validity was evidenced by moderate correlations between weighted severity and intrusiveness intervention.

Case 2. Verbal and physical aggression as measured by the OAS-MNR (Alderman et al., 1997). Staff in the setting were trained in the recording of events as they occurred across the following categories: Verbal aggression, Physical aggression towards objects, Physical aggression towards self, and Physical aggression towards others (with four sub-categories within each of increasing severity).

Continuous recording of target behaviours provided baseline data against which the novel intervention was tested. Recorder blindness to intervention onset increased confidence in the attributions of change.

Statistical analysis

The start date of the intervention was randomly assigned within a window of two weeks by allocating the start date to one of three envelope-concealed consecutive Mondays. This indicated two potential statistical approaches, randomisation statistics (Todman & Dugard, 2001) or non-overlap of all pairs (NAP; Parker & Vannest, 2009). The NAP statistic was chosen to compare baseline and intervention. NAP is a statistical test of difference in scores between two or more phases of data collection. It has evidenced ability to discriminate among typical single-case research results and has been correlated with established indices of magnitude of effect including Cohen's *d* (Cohen, 1988, Parker & Vannest, 2009).

Participants

Case 1 was a 33-year-old male with a 21-year history of severe TBI. Emotional dysregulation, learning support needs and conduct disorder followed diffuse brain injury incurred in a pedestrian versus motorcycle road traffic accident. Emotional dysregulation resulted in presentation to psychiatric services with self-injury as a coping strategy for severe anxiety at age 19. Emotional dysregulation also led to aggressive behaviour on occasion and he was co-convicted in a murder case (age 19). At the start of the trial he was injuring himself by taking sharp objects and lit cigarettes to his hands and forearms. He described an antecedent of intrusive recollections which led to increasing anxiety dissipated by self-injury.

Persisting neuropsychological impairments were identified at the time of the current study. These included impairment of attention (Test of Everyday Attention; Robertson, Ward, Ridgeway, & Nimmo-Smith, 1994); a general memory index (Rivermead Behavioural Memory Test) (RBMT; Wilson et al., 2008) in the extremely low range; and borderline intellectual functioning (Wechsler Adult Intelligence Scale-IV) (WAIS-IV; Wechsler, 2008). No perceptual abnormalities were evident. The Behavioural Assessment of

Dysexecutive Syndrome (BADS; Wilson, Alderman, Burgess, Emslie, & Evans, 2003) indicated a score in the low average range. Poor executive/attentional control directly related to emotional function: He had great difficulty controlling emotive thoughts and experienced frequent intrusions which were often associated with anxiety. The misattribution of anxiety symptoms was explained as paranoid ideation. Self-injury persisted as a coping strategy for difficulties with emotional regulation.

At the time of the trial he was prescribed Olanzapine 20 mg at 22:00; Propanolol 40 mg at 8:00, 12:00 and 18:00; Diazepam 5 mg at 18:00; Mirtazepine 30 mg at 22:00; Lamotrigine 100 mg at 8:00 and 22:00; Valproic acid at 8:00, 12:00 and 22:00; Procyclidine 5 mg at 8:00 and 22:00; Hyoscine Butylbromide 10 mg QID; Folic acid 5 mg at 8:00; Lactulose 3.7 g at 8:00 and 22:00. The prescription had been long standing and was kept constant through the experimental intervention.

Case 2 was an 18-year-old male with a 4-year history of TBI sustained as the front passenger in a car involved in a head-on collision. A post-traumatic amnesia of 4 weeks indicated extremely severe categorisation. An intracranial pressure monitor was inserted but no other neurosurgery took place. Extensive physiotherapy was required for walking. On return to community living he manifested severe disinhibited aggression when thwarted in desires. He used substances in an uncontrolled manner and had become homeless due to difficulties his family had dealing with his aggressive behaviour.

Case 2 was estimated to be in the average range of premorbid intelligence. He had a normal digit span but was frequently distracted during testing, particularly by emotionally significant thoughts. Standardised memory assessment (Rivermead Behavioural Memory Test; Wilson et al., 2008) revealed that he was in the borderline range of new learning. Prospective memory was in the impaired range. He also tended to falsely recognise visual items as previously presented. There were no visuospatial deficits (WAIS-IV; Wechsler, 2008). He had average range executive function overall but disinhibition was elicited in several subtests (BADS; Wilson et al., 2003).

At the time of the study Case 2 was prescribed Zimovane 3.75 mg at 22:00 and Symbicort turbohaler 200/6 120 and as required: Chlorpromazine 25 mg for agitation (administered nine times, all in baseline); and Lorazepam 0.5 mg as required (administered twice in baseline, twice in intervention).

RESULTS

Case 1

Self-injury was recorded using the OAS-MNR, which includes weightings for severity of injury caused along a 4-point scale. These scores in baseline

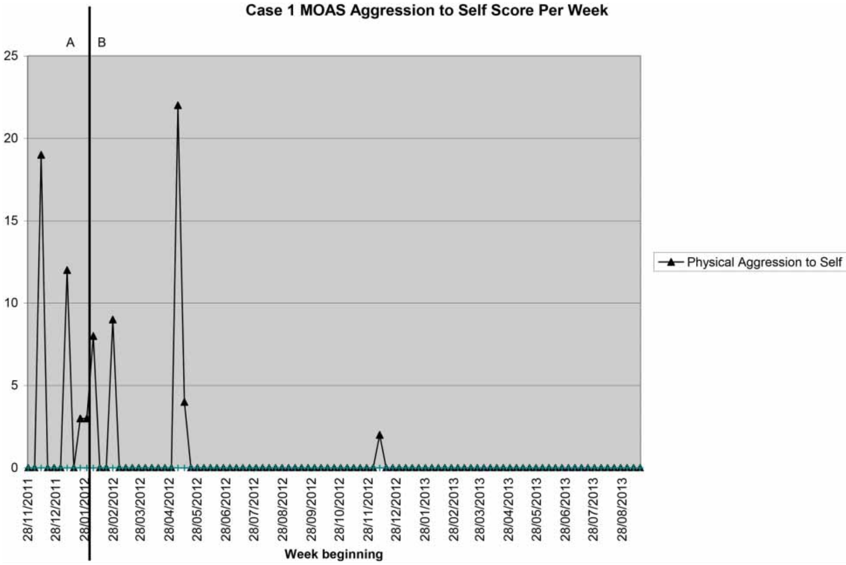

Figure 2. Case 1. Self injury OAS-MNR (or MOAS) baseline and intervention data.

(60 data points) were compared with scores during the emWave2 intervention (70 data points) for analyses reported. Figure 2 shows the weekly totals of these data in A and B, and to data point 570 to demonstrate effect maintenance. Case 1 elected to continue use and so there was no return to baseline.

Comparisons between baseline and intervention periods revealed that the effect was non-significant, NAP $= 0.65$, $p = .14$. The lack of significance seems related to the lag in the effect from the start of the intervention. This may have reflected the time taken to learn to use the technology to support reduced arousal.

Reversal to baseline was considered but given the apparent clinical effect on a severe target behaviour, it was decided within the team to allow continued use. The service user found emWave2 a useful adjunct to treatment as usual and continued to use it for over one year post-intervention.

Treatment as usual is a multi-disciplinary approach involving input from occupational therapy, speech therapy, nursing, psychiatry and psychology. Standard psychological therapy involves attendance at a number of therapeutic groups, for example, anxiety management. In addition, one-to-one therapy is provided as required. The emWave2 appeared to be a useful adjunct to treatment as the service user was able to use the device independently with only minimal guidance, instilling a sense of control. In addition, as a young man he was very technologically minded and felt comfortable using the device.

Clinical outcome was more positive. Case 1 has now been using the device daily for over one year. The last recorded episode of self-injury was at 2 months post-treatment onset.

Case 2

The Overt Aggression Scale Modified for Neurorehabilitation (OASMNR; Alderman et al., 1997) was used (recording multiple episodes of behaviours). This revealed a total score over the baseline (33 daily data points) of 795. The behaviours which contributed to this score (graphed over time in Figure 3) included 175 incidents of verbal aggression, 79 incidents of physical aggression to objects and six episodes of physical aggression to persons.

In the intervention period the total OASMNR score in the intervention phase (24 daily data points) was 191. There were 61 incidents of verbal aggression, seven incidents of physical aggression to objects and three incidents of physical aggression to self. The total OASMNR data are shown in Figure 3 (Figure 3 includes up to intervention data point 50 to demonstrate maintenance of effect).

NAP was used to compare baseline and intervention (NAP 0.85, $p = .001$; Vanest, Parker, & Gonen, 2011). An effect size was estimated (after Parker & Vannest, 2009) using the formula Cohen's $d = 3.464^{*}(1\text{-}\sqrt{(1\text{-NAP})/.5}) = 2.683$ (after Parker & Vannest, 2009) and is deemed a large effect in this

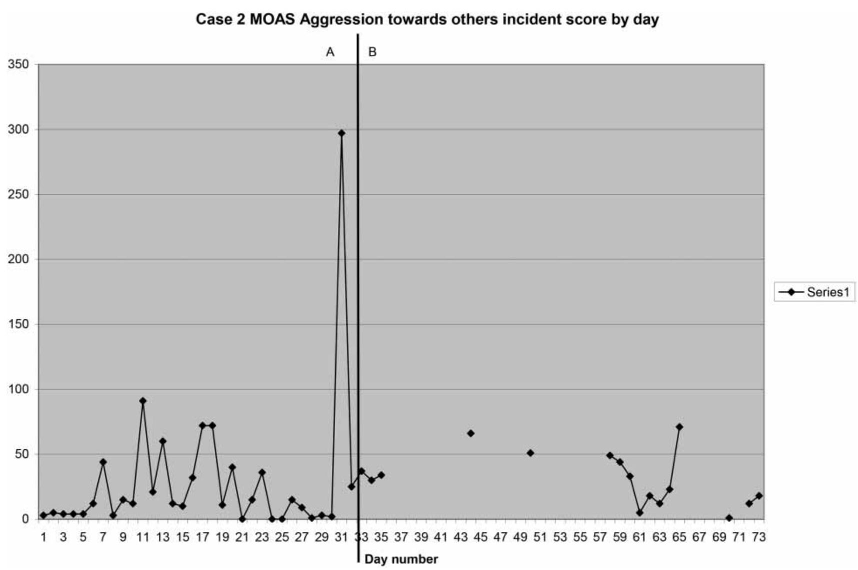

Figure 3. Case 2. Challenging behaviour OAS-MNR (or MOAS) baseline and intervention data.

case. Reversal to baseline was again considered but given the exploratory nature of the study and the apparent positive effect on behaviour, it was not deemed ethical to do so.

Clinically, Case 2 reported increased subjective well-being while using the device and afterwards. He purchased an emWave2 on discharge from the rehabilitation centre for continued use. His mother's report on the period after the rehabilitation stay was that the service user had had, "Three good months . . . none of the anger of before . . . polite . . . like [he was] before the accident."

DISCUSSION

Single-case methodologies (SCMs) were used to provide preliminary evidence of effectiveness for a novel intervention in challenging behaviour after severe brain injury. Both cases presented with impulsive aggression. This was directed towards the self during episodes of anxiety in Case 1 and towards others in Case 2. In Case 1 the effect of the emWave2 biofeedback intervention was not statistically significant but the target behaviour was eliminated. Lack of statistical significance appears due to a lag between treatment onset and effect (see Figure 2) or limited data points in baseline (the participant was admitted to the hospital with a history of recent frequent self-injurious behaviour but we did not have access to the data points from the previous setting).

In Case 2 the effect was statistically significant. There appeared to be a more immediate effect in Case 2. In both cases the treatment was ecologically significant and both users of the biofeedback technology attributed increased well-being to the device and elected to continue use. These improvements were perceived differently in each case. In case 1, an increase in the ability to recognise frustration within the body was described. This led to relaxation strategies being utilised before reaching the point of impulsive self-harm. In case 2, a sense of self-efficacy was described in which this individual was more in control of his behaviour. He felt that the device allowed him to maintain a calm state, therefore reducing aggressive outbursts.

There are several possible interpretations of the association of biofeedback use and reduction in challenging target behaviours. Difficulty recognising and naming one's emotional states has been linked to challenging behaviour. Alexithymia predicted impulsive aggression in a sample of veterans with difficulties managing anger (Teten, Miller, Bailey, Dunn, & Kent, 2008). Manninen, Therman, Suvisaari, Ebeling, Moilanen, and Joukamaa (2011) investigated the association between alexithymia and psychiatric symptoms among adolescents living in a closed institution because of severe behavioural problems. Scores on the Toronto Alexithymia Scale (Bagby, Parker, &

Taylor, 1994) of 47 adolescents were correlated with self-reported aggression and were significantly lower than age and demographically matched controls.

The emWave2 device enabled the participants to better differentiate physiological signs of stress from states of high coherence (increased heart rate variability). Alexithymia was a facet of both participants' clinical presentation. It is thus possible that the device reduced challenging behaviour by improving identification of physiological signs of negative emotional states allowing prevention of emotional escalations. Before and after administration of an alexithymia scale might allow an empirical test of this suggested mediator of effect.

The Risk of Bias in *N*-of-1 Trials Scale (RoBiNT; Tate et al., 2013) was used to critique the design of this study, highlighting a number of limitations. The design used (A-B) only contained one phase change, therefore decreasing internal validity. An A-B-A design (2 phase changes) was considered but the return to baseline was not considered ethical due to the beneficial effect apparent in the treatment phase. An A-B-A-B design would seem justifiable in future research. As participants were learning a new way of relating to physiological states, there is a possibility of treatment carry-over, suggesting that a return to baseline would not necessarily be associated with target behaviours returning to baseline rates. We suggest a return to baseline after four weeks (20 treatment sessions) with re-introduction of the treatment should target behaviours re-emerge.

That the treatment involved a physical device meant that it was not possible for the therapist and patient to be blinded. However, this limitation was offset by the blinding of the assessors, i.e., the support workers who recorded the behavioural data were unaware of the intervention phase. The absence of raw data associated with each treatment session could is also a limitation. However, the presence of the therapist during these sessions did ensure that the emWave2 was attended to and used in accordance with the instructions.

The use of SCMs in the management of behavioural problems has a relatively long history (Wood, 1987). The current study utilised a standardised assessment measure (OASMNR; Alderman et al., 1997) to quantify the level of challenge in terms of aggression towards the self and others. Behavioural counts of the challenging behaviour in question might also have been used.

Moving beyond challenging behaviour, behavioural observation measures and SCM can be applied to many areas of clinical need. In mental health/emotional work, counts of activities that a person has engaged in may be used to measure change in behavioural activation. An observation measure such as the Hamilton Depression Rating Scale (Hedlund & Viewig, 1979) can be repeated in baseline and intervention phases. We discuss actigraphy and physiological monitoring below to this same end. In working with anxiety, subjective units of distress (SUDS) have had a long use in single case experiments (Wolpe, 1969). Sleep problems might be measured by sleep charts completed by observers or self-report diaries (Morin & Espie, 2003).

SCM can be applied to the acquisition of new behaviours. Rehabilitation is about learning new sequences of behaviour to complete everyday activities (Langan-Fox, Grant, & Anglim, 2007). The focus on measurable behaviour in rehabilitation is therefore a useful level of analysis. The SCM is thus a useful tool to ascertain whether or not a goal is being reached or if the approach needs to be reformulated. Difficulties with sequence performance are frustrating. Thus interventions which aim to improve performance may also reduce frustration and thereby challenge. Checklists of behaviours which must be performed to reach the end are a useful means of assessing the effect of an intervention (O'Neill, Best, Gillespie, & O'Neill, 2013). Similarly, disorientation may underpin challenge. A repeatable measure such as the Galveston Orientation and Amnesia Test may be administered (Levin, O'Donnell, & Grossman, 1979).

Wearable automatic data acquisition systems are set to become an important data source which can be subjected to SCM. Movement sensors, a first generation of wearable data capture, are utilised in actigraphy, the quantification of movement to give data points in sleep disorders. Their use in mood disorders such as depression and bi-polar presentations, where mood can be inferred from activity level, will allow individualised measurement of the efficacy of interventions. Gathering 24 hour movement data through observation is not practical and self-report is unreliable. However, a wearable monitor that automatically records movements over time might be useful in detecting the effectiveness of an intervention to increase the person's behavioural activation. In a rehabilitation context, movement of an impaired limb might be monitored in baseline and intervention using such a system.

Physiological measures add to the accuracy of inference of emotional state (Picard, Vyzas, & Healey, 2001). Systems detecting and recording movement, location, galvanic skin response (GSR) and heart rate would allow multiple data streams which together might describe both behaviour and emotional response. Recent advances mean that this data could also be available in real time. The power of this paradigm to ascertain the effectiveness of an intervention on (a) behaviour, (b) emotional state, (c) arousal level, or a combination of these would give clinicians a powerful new tool.

In the context of neurobehavioural rehabilitation, physiological monitoring devices would allow evidence that a specific pharmacological agent reduced the frequency of challenging behaviour but maintained behavioural activation (O'Neill, Findlay, & Goodfellow, 2012). Or, if behavioural activation was changed, allow that to be factored into clinical decision making. We might also envisage testing the effects of simple feedback. If persons with brain injury have difficulty monitoring their arousal levels, feedback on current arousal level or detected emotional valence might in itself help with the regulation of emotion.

The availability of cheap and efficient recording, processing and feedback of large numbers of behavioural and biometric data is allowing system users to become aware of indices of health and well-being. The informed individual utilises feedback from their own recordings to modify behaviour that, in turn, affects the data monitored. This is akin to an extension of the biofeedback from 10–20 minutes per day, as reported in the current study, to continuous biofeedback. In this paradigm, the SCM may offer greater usefulness than group comparison. Automatic measurement, expert system formulation and feedback interventions tailored to the individual might allow closure of the feedback loop absent in persons with alexithymia.

Rehabilitation after brain injury is a relatively new discipline and one where we have yet to outline all potentially useful interventions. Innovation is still required to meet our clients' needs. If study designs were ranked by their potential for new discoveries, then anecdotal evidence would be at the top of the list, followed by observational studies and RCTs (Vandenbroucke, 2008). The SCM allows us to continue to innovate in a space requiring this. Technologies are developing rapidly and when exploring innovative applications in support of the mental functions, SCM are indicated to gather preliminary efficacy data.

Technologies to support specific aspects of function can gather and feed back large numbers of processed data, generating large datasets for analysis. Gathering continuous data may yet allow the interrupted time series to be epistemologically superior to control trials with their reliance on specific time point data collection. Technology-gathered continuous data streams would allow assessment of the effect size of intervention, determination of a learning curve, habituation curve, dose-response relationship, and maintenance over time and after withdrawal.

An empirical comparison of randomised control trial findings and single case design findings may be possible. If an RCT were to measure both the traditional pre-intervention, post-intervention and follow-up data points for comparison between groups, as well as several measurements in baseline, intervention and follow up, we might then determine the effect size of the intervention from the RCT and simultaneously the effect size of the intervention in the experimental group against itself in baseline. We might then determine how many of the experimental group needed to participate to ascertain robustly that effect size.

Single-case methodologies have had a varied standing in evidence-based medicine. Developments in design (e.g., Tate et al., 2013), repeatable measures, analysis and interpretation (Parker & Vannest, 2009) have improved confidence in evidence from single case methodologies. This report begins our exploration of the use of efficient reliable physiological data recording that can function both as a measurement and a feedback intervention to reduce the disabling aspects of emotional dysregulation.

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