Judge Rotenberg Educational Center, Inc.

Submission to Docket FDA-2014-N-0238

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Neurological Devices Advisory Panel Meeting

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I. EXECUTIVE SUMMARY

The Judge Rotenberg Educational Center, Inc. ("JRC" or the "Center") is an educational and treatment center that provides treatment and educational services to disabled children and adults with severe behavior disorders and other disabilities such as developmental disabilities and emotional disorders. The Center is often a place of last resort for patients that have been rejected or discharged from other institutions due to the severity of their behavioral problems which could not be adequately controlled by medications, positive reinforcement therapies or restraints. Patients at JRC are treated with standard of care clinical methods and provided educational opportunities and a safe learning and living environment. There are a total of 241 patients currently enrolled at the Center.

For patients with severe behavioral disorders involving aggressive and/or self-injurious behaviors and for whom these behaviors have not been adequately or safely controlled through positive reinforcement and/or medications, the Center may use aversive conditioning therapy as a supplement to positive reinforcement behavior therapies with the Center's Graduated Electronic Decelerator ("GED") devices. These patients exhibit harmful and self-destructive behaviors such as head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, destroying furniture and school equipment, punching their fists through glass windows, running into traffic, jumping out of windows, and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects.

These aversive conditioning devices are a safe treatment option and used only in extreme cases where patients are a danger to themselves and others **and** where all other treatment options have failed. There are no appropriate and safe alternatives for this limited group of patients. Of the 241 patients currently enrolled at JRC, 71 patients are indicated for use of aversive therapy and only 60 patients are currently utilizing GED devices.

Treatment with the GED is intended to be used in conjunction with positive reinforcement behavior therapies and in response to harmful behaviors. The device is worn by the patient for whom its use has been ordered by a Massachusetts Probate and Family Court. When activated, the GED provides a low grade, but assertive electric shock to the surface of the patient's skin. Specifically, the device sends a two second electric shock to an electrode attached to the surface of the patient's skin on the inner/outer forearm, upper arm, upper thigh, calf, torso/stomach, palms of hands, soles of feet, or upper/outer quadrant of the buttocks.

Importantly, before the GED can be used in the treatment of a patient at JRC, the following steps, among others, are required to take place:

1. Other therapies used to treat the patient have failed;
2. The parent/guardian must provide written informed consent;
3. A Ph.D.-level licensed psychologist or a Ph.D.-level Board Certified Behavior Analyst must prepare an appropriate treatment plan for the patient;
4. A peer review committee must review the plan and deem it appropriate;
5. The school district or agency that referred the patient to JRC also must approve the treatment plan and incorporate it into the patient's Individualized Education or Service Plan;
6. A physician must certify the absence of medical contraindications to the use of the GED devices;
7. A human rights committee must approve the treatment plan; and

8. The patient must be assigned by a Massachusetts Probate and Family Court his or her own court-appointed independent counsel who may hire court-funded experts, as appropriate, to evaluate the patient and oppose the treatment in court, if warranted, and the treatment plan must be authorized by a Massachusetts Probate and Family Court.

Each application of the GED device is carefully monitored by Center staff and all patients receiving a stimulus from the device are closely evaluated by the nursing staff within 24 hours of receipt of a shock. These and other numerous controls in place ensure the safety of students receiving aversive therapy. The use of the devices has a very safe record at JRC, with no significant adverse events and no substantial risk of harm presented.

Patients are routinely monitored on a weekly basis for physical and mental well-being as well. Staff are further instructed to carefully monitor any patients receiving aversive therapies for changes in behavior such as increases in aggression, escape behaviors, emotional reactions, sleep difficulties, and any other physical or emotional reaction or change

JRC firmly believes that these controls are sufficient to continue to ensure the safety of the patients being treated with the device, and that the benefits of the continued treatment with the device far outweigh its risks. Due to the unprecedented treatment benefits of the GED, these patients are currently free from the severe pain and bodily injury caused by their violent self-abuse while they are receiving an education, living skills training, job training, and a quality of life that was not possible for them before treatment with aversive conditioning. Additionally, of the 241 current patients at the Center, 23 have been successfully transitioned from aversive therapy and do not currently require the GED device to control the self-injurious, aggressive and harmful behaviors which originally prompted the therapy.

As noted above, every therapy currently available, including cocktails of psychotropic medications and positive reinforcement techniques have failed to adequately and/or safely curb these patient's extreme aggressive and self injurious behaviors. Further, no short or long term side effects of aversive conditioning therapy has been observed by JRC based on follow-up evaluations and routine physical and mental health monitoring by the JRC medical staff. The benefits of aversive conditioning in protecting these patients from their destructive behaviors outweigh the potential risks presented by such therapy. In light of these patients' conditions, aversive conditioning does not present an unreasonable and substantial risk of harm.

II. BACKGROUND

A. Available Therapies for Treatment of Severe Behavior Disorders

For patients presenting with severe behavior disorders involving aggressive and self-injurious behaviors, the control of such destructive behaviors is necessary to prevent further injury to themselves and others. When other behavior modifications therapies such a positive reinforcement has failed, the other treatment options include cocktails of psychotropic medications and physical restraints. Additionally, certain institutions around the world offer therapy with aversive conditioning devices.

Mechanical restraints such as straitjackets, straps, and handcuffs have long been used to control these patients. The American Medical Association ("AMA") recognizes that in certain cases, physical or chemical restraint may be necessary. In OPINON 8.17 – USE OF RESTRAINTS the AMA states:

> All individuals have a fundamental right to be free from unreasonable bodily restraint. Physical and chemical restraints should therefore be used only in the best interest of the patient and in accordance with the following guidelines:
>
> 1) The use of restraints, except in emergencies, may be implemented only upon the explicit order of a physician, in conformance with reasonable professional judgment.
>
> 2) Judgment should be exercised in issuing pro re nata (PRN) orders for the use of physical or chemical restraints, and the implementation of such orders should be frequently reviewed and documented by the physician.
>
> 3) The use of restraints should not be punitive, nor should they be used for convenience or as an alternative to reasonable staffing.
>
> 4) Restraints should be used only in accordance with appropriate clinical indications.
>
> 5) As with all therapeutic interventions, informed consent by the patient or surrogate decision maker is a key element in the application of physical and chemical restraints, and should be incorporated into institutional policy.
>
> 6) In certain limited situations, it may be appropriate to restrain a patient involuntarily. For example, restraints may be needed for the safety of the patient or others in the area. When restraints are used involuntarily, the restraints should be removed when they are no longer needed. (I, IV)[1]

However, use of physical restraints could have serious psychological and physical effects and has led to death in some facilities. Accordingly, there is a recent trend toward moving away from the use

[1] AMA Code of Medical Ethics, Opinion 8.17 – Use of Restraints. available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion817.page (last accessed April 14, 2014)

of restraints. The July 2003 report from the President's New Freedom Commission on Mental Health states:

> Seclusion and restraint are safety interventions of last resort; they are not treatment interventions. In light of the potentially serious consequences, seclusion and restraint should be used only when an imminent risk of danger to the individual or others exists and no other safe, effective intervention is possible.[2]

The Substance Abuse and Mental Health Service Administration (SAMHSA) provides an entire guidebook on reducing the use of restraints in mental health care facilities, *Roadmap to Seclusion and Restraint Free Mental Health Services*, which states

> The Federal Government, Joint Accreditation Commission of Hospital Organizations (JACHO), consumer and family organizations, professional organizations, and State mental health authorities are all invested in the reduction and elimination of seclusion and restraint as a practice within treatment settings[3]

This document further states:

> Seclusion and restraints do not keep people safe. The harm is well documented; not only the physical harm, but also the emotional and mental harm. Restraints actually harm and can cause death. Broken bones and cardiopulmonary complications are associated with the use of seclusion and restraint (FDA, 1992; NYS OMH, 1994).[4]

Further, the use of alternative methods for treating severe aggressive and self-injurious behaviors, namely medications, can have significant consequences. The side effects of antipsychotic medications, can include, for example, major weight gain,[5] severe sedation, acute and chronic extrapyramidal syndromes (e.g. tardive dyskinesia, akathisia, dystonia, parkinsonism),[6] neuroleptic

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[2] The President's New Freedom Commission on Mental Health, July 22, 2003, letter *Achieving the Promise: Transforming Mental Health Care in America*, page 34, available at http://govinfo.library.unt.edu/mentalhealthcommission/reports/FinalReport/downloads/FinalReport.pdf (last accessed April 14, 2014)

[3] Roadmap to Seclusion and Restraint Free Mental Health Services, available at http://store.samhsa.gov/shin/content/SMA06-4055/SMA06-4055-B.pdf (last accessed April 14, 2014)

[4] *Id*. at 11.

[5] Allison, D.B., Mentore, J.L., Moonseong, H., Chandler, L.P., Capelleri, J.C., Infanted, M.C. and Weiden, P.J. (1999). Antipsychotic-induced weight gain: A comprehensive research synthesis. *America Journal of Psychiatry, 156 (11),* 1689-1696.

Correll, C.U., Manu, P., Olshanskiy, V., Napolitano, B., Kane, J.M., & Malhotra, A.K. (2009). Cardiometabolic Risk of Second-Generation Antipsychotic Medications During First-Time Use in Children and Adolescents. *Journal of the American Medical Association, 302(16),* 1765-1773.

[6] Tarsy, D., Lungu, C., & Baldessarini, R.J. (2011). Epidemiology of tardive dyskinesia before and during the era of modern antipsychotic drugs. In Weiner and Tolosa (Eds.), *Handbook of Clinical Neurology: Hyperkinetic Movement Disorders. Volume 100. (pp. 601-616).* Edinburgh: Elsevier.

Marder, S.R., & van Kammen, D.P. (2005). Dopamine receptor antagonists (typical antipsychotics). In B.J. Saddock & V.A. Saddock (Eds.), *Comprehensive Textbook of Psychiatry* (pp. 2817-2838). Philadelphia, PA: Lippincott Williams & Wilkins.

malignant syndrome,[7] sexual dysfunction,[8] prolactin elevation,[9] sudden cardiac death,[10] nocturnal enuresis,[11] addiction, increased likelihood of diabetes, and/or life-shortening metabolic changes.[12]

Importantly, medications only mask issues, and do not cure the underlying disease. Patients must be permanently placed on such medication in order to control their behaviors. However, experts in the field of mental health have recognized that "Long-term effects have not been studied well enough for many psychotropic medications."[13]

In contrast to the use of restraints and large doses of psychotropic medications, aversive conditioning therapies allow patients to learn productive behaviors to replace their dangerous behaviors, perform daily life tasks and interact with others, allowing for education and training opportunities and therapy. As discussed in detail in Section V of this document, there has been no evidence of harmful short or long-term side effects regarding the use of aversive therapies. The use of aversive conditioning devices is appropriate for a limited patient population who exhibit extreme aggressive and self-injurious behaviors posing a danger to themselves and others, where other treatment options have previously failed.

B. Regulatory History of JRC's GED Devices

The GED is an aversive therapy device developed by JRC that provides cutaneous electrical stimulation to reduce extreme aggressive, disruptive or self-injurious behaviors. The device is produced at and used only for patients enrolled at the Center and is not distributed or marketed for sale.

JRC received 510(k) clearance for the first GED model on December 5, 1994 (K911820). Since that time, JRC has developed newer versions of the GED device, and currently uses two versions of the device, the GED-3A and the GED-4.

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[7] Adnet, P., Lestavel, P., and Krivosic-Horber, R. (2000). Neuroleptic malignant syndrome. *British Journal of Anaesthesia, 85(1),* 129-35.

[8] Serreti, A., & Chiesa, A. (2011). A meta-analysis of sexual dysfunction in psychiatric patients taking antipsychotics. *International Clinical Psychopharmacology, 26 (3), 130-140.*

[9] Rosenbloom, A.L. (2010). Hyperprlactinemia with antipsychotic drugs in children and adolescents. *International Journal of Pediatric Endocrinology, 2010,* 1-6. doi: 10.1155/2010/159402

[10] Ray, W.A., Chung, C.P., Murray, K.T., Hall, K., & Stein, M.B. (2009). Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death. *The New England Journal of Medicine, 360*, 225-235.

[11] Harrison-Woolrych, M., Skegg, K., Ashton, J., Herbison, P., & Skegg, D.C.G. (2011). Nocturnal enuresis in patients taking clozapine, risperidone, olanzapine and quetiapine: comparative cohort study. *British Journal of Psychiatry, 199,* 140-144. doi: 10.1192/bjp.bp.110.087478

[12] For a history and evaluation of the use of psychotropic drugs with individuals with intellectual disabilities, see Levitas, A. S. & Hurley, A. D. (2006a). The history behind the use of anti-psychotic medications in persons with intellectual disability: Part I. *Mental Health Aspects of Developmental disabilities, 9,* (26-32). http://www.judgerc.org/LevitasAntipsychoitc.pdf and Levitas, A. S. & Hurley, A. D. (2006b). The history behind the use of anti-psychotic medications in persons with intellectual disability: Part II. *Mental Health Aspects of Developmental disabilities, 9,* (93-98). Both articles as well as a third article by the same authors in 2008 are available at http://www.judgerc.org/LevitasAntipsychoitc.pdf. For an article by William Carpenter, M.D. that points out that antipsychotic drugs can take years off of a person's life, see Carpenter, W., (2007). Choosing the right antipsychotic. *The Carlat Psychiatry Report, Vol. 5, No. 3,* 4-5 (also available at http://www.judgerc.org/CarpenterArticle.pdf).

[13] The President's New Freedom Commission on Mental Health *supra* at 71.

Following an inspection by the U.S. Food and Drug Administration ("FDA" or the "Agency") in 2000, JRC was advised by the Agency that the GED devices were not subject to FDA's 510(k) requirements. Specifically, FDA stated that,

> After discussions with NEW-DO compliance branch and CDRH, it was determined that the firm is exempt from 510(k) notices, and the device is considered to be within the practice of medicine.

This statement from FDA is provided in **Attachment 1**. JRC continued to manufacture, service, and use the GED devices under the practice of medicine for some 10 years without any communication with FDA.

Despite the Agency's 2000 position as to the regulatory status of the GED, FDA conducted an inspection of JRC again in November 2010, which resulted in issuance of a Form FDA 483 at the end of that inspection. In a subsequent Untitled Letter received by JRC on May 23, 2011, FDA stated that the Agency has changed its position with respect to the regulatory status of the GED and that clearance of a new 510(k) is required for use of the GED-3A and GED-4. The Center subsequently received a second Untitled Letter on July 2, 2012, and a Warning Letter received on December 7, 2012.

JRC undertook the redesign of the devices, at great expense, subsequent to these exchanges with FDA in order to meet updated standards. However, a new 510(k) notice has not yet been filed for these updated devices in accordance with certain ongoing communications with FDA. While the 510(k) notice was ready for submission, the agency requested during a January 9, 2013, meeting that JRC first file a pre-submission in order to discuss the content of the 510(k) notice. In an effort to work cooperatively with FDA, the Center filed this pre-submission (Q130112) on February 1, 2013. A meeting was scheduled by FDA for March 25, 2013. In advance of the meeting, the agency requested further detailed information regarding the device output, which the Center provided. However, this meeting was cancelled by the agency five days prior to the meeting. Despite additional requests from the Center to schedule this meeting, the Agency never responded with a new meeting date and did not provide the Center with comments on the pre-submission materials. Since FDA has specifically requested that the company submit a pre-submission to provide the Agency with the opportunity to provide comments on the content of the 510(k) notice prior to filing such notice, and since the Agency never provided such comments, the Center never filed the 510(k) notice to address the newly designed devices. It should be noted that the Center also has not used the modified devices that will be covered by the proposed 510(k) notice. Moreover, the Center also offered to submit an Investigational Device Exemption (IDE) application to study the devices in a clinical trial. FDA never provided an answer to this proposal. In fact, no further communication from FDA was received regarding the GED devices at all. The Center only became aware of this panel meeting after it was announced in the Federal Register on March 27, 2014. Nevertheless, the Center is prepared to file the 510(k) notice when notified by FDA that it is now ready for such submission. Nevertheless, JRC continues to believe that FDA was entirely correct that no 510(k) notice is necessary since these devices are exempt from premarket notification as the practice of medicine as provided under the Federal Food, Drug, and Cosmetic Act.[14]

[14] 21 U.S.C. § 396.

III. DEVICE DESCRIPTION

The GED is an aversive therapy device that provides cutaneous electrical stimulation to reduce extreme behaviors which are likely to cause self injury or injury to others. The GED device is mobile, battery operated, and worn by a patient.

The device is remotely activated to deliver an electrical stimulation to patients when triggered by trained institution staff who directly observe the behavior that has been identified for treatment by a Center clinician. In practice, these behaviors have been operationally defined by a doctoral level clinician and approved by Probate Court for each specific patient. The device is used in conjunction with other positive reinforcement behavior therapies and it is intended that the patients will learn sufficient control skills during treatment that they will eventually be able to transition off use of the aversive conditioning devices. The GED device is used only by the Judge Rotenberg Educational Center, Inc. ("JRC" or "the Center") to treat students enrolled at the Center and is not commercially distributed.

The device includes a Stimulus Generator for creating the stimulation, a skin contact Electrode which delivers the stimulation to the patient, and a Remote Activator for activating the Stimulus Generator. Further information on each of these components is provided below.

The two versions of the device, GED-3 and GED-4A, have exactly the same design, with the only difference being an increased output from the Stimulus Generator.

A. Stimulus Generator

The Stimulus Generator is used to create an electric stimulus, which is delivered to the patient through a skin-contact electrode. An electrical cable carries the signal from the Stimulus Generator to the electrode. Each Stimulus Generator is paired with a specific Remote Activator that allows the operator/therapist to activate the GED device and deliver an aversive stimulus to the patient.

The stimulus output waveform is not adjustable and is a fixed duration series of DC pulses at 80 Hz with a fixed 25% duty cycle. Both the GED-3 and the GED-4A produce a maximum 1.85 second train of square waves and a pulse repetition frequency of 80 pulses per second.

Table 1. GED Output parameters

Nominal Output Characteristic (5 kOhm load)	GED-3	GED-4A
Amps	12 mA	42 mA
Root mean square (RMS) pulsed DC voltage output	60 Vrms	120 Vrms
Duty cycle	25%	25%
Pulse repetition rate	80.0 Hz	80.0 Hz
Duration of Stimulus	2.0 sec	2.0 sec

Unlike A/C currents which can lead to ventricular fibrillation at low levels and cause severe contraction of the muscles, the GED device delivers DC current. Additionally, the low voltage levels of the GED devices avoid the potential for thermal injury to skin and underlying tissue. As can be seen from Table 2, below,

Table 2. Effects of Direct Current on the Body[15]

Effects	Direct Current	
	Men	Women
Slight sensation on hand	1	0.6
Perception threshold, median	5.2	3.5
Shock—not painful and no loss of muscular control	9	6
GED-3	12mA	
GED-4A	42mA	
Painful shock—muscular control lost by 0.5%	62	41
Painful shock—let-go threshold, median	76	51
Painful and severe shock—breathing difficult, muscular control lost by 99.5%	90	60
Possible ventricular fibrillation:		
Three-second shocks	500	500
High-voltage surges (Energy in joules, i.e., watt-seconds)	50 J	50 J

The electrical output of the GED devices is categorized as 'Surprise' or 'Reflex Action' on the Neitzel Table, based on *Nave & Nave, Ch 14, Table 14-1*[16] and *Neitzel*, *Table 2*[17] as follows:

DC (mA)	Physiological Effects
0-4	Perception
4 – 15	Surprise (Reaction)
15 – 88	Reflex Action (Let Go)
80 – 160	Muscular Inhibition
160 – 300	Respiratory Block
>300	Usually Fatal

The patient wears a waist (fanny) pack or backpack that holds the GED Stimulus Generator and Electrode Cable Assembly on the patient. These components are off-the shelf and are not manufactured by the Center.

B. Electrode

The Stimulus Generator is connected to an electrode set to provide the cutaneous skin shock to the patient.

[15] Charles F. Dalziel, *Deleterious Effects of Electric Shock*, p. 24. Presented at a meeting of experts on electrical accidents and related matters, sponsored by the International Labour Office, World Health Office and International Electrotechnical Commission, Geneva, Switzerland, October 23–31, 1961. available at http://www.electriciancalculators.com/dalziel/dalziel_study.pdf (last accessed April 14, 2014)

[16] Nave & Nave, Physics For the Health Sciences, 3rd Ed, W. B. Saunders, 1985

[17] Neitzel, Dennis. *The Hazards of Electricity - Do You Know What They Are?*

The GED-3 can be used with two different electrode configurations:

1) A “concentric” electrode which consists of a stainless steel button surrounded by a stainless steel ring. The total size of the electrode assembly is approximately one inch.

2) A “distanced” electrode configuration consisting of two distinct stainless steel electrode contacts which are spaced 4 to 6 inches apart.

The GED-4A only uses the distanced electrode configuration (configuration 2) described above.

As determined by the doctoral level clinician who has direct responsibility over the patient’s care, the Electrode may be placed in the following locations: palm of the hand; sole of the foot; outer thigh, inner thigh, outer arm; inner arm; outer forearm; inner forearm; torso (not over spine or heart); calf; lower back (not on spine); upper buttocks. The User Manual and Staff Training Manual includes a warning to never place the electrode on the chest or breasts, genitals, head, top of hand, top of foot, the lower quadrant on the buttocks of a patient, or on any area of skin known to be unusually sensitive in that patient to skin irritation or subject to allergic reaction to contact with stainless steel.

The Electrode is connected to the Stimulus Generator through a dedicated cable and attached to a patient using a strap.

C. Remote Activator

The Remote Activator is carried by Center staff and used to activate the Stimulus Generator of a patient as needed to treat harmful and dangerous behaviors. The Remote Activator incorporates a wireless transceiver that sends a stimulation activation signal to the companion transceiver embedded in the GED unit. Each Remote Activator is paired to a single Stimulus Generator.

Each Remote Activator has a photograph of the patient who is wearing the associated Stimulus Generator to ensure that the proper patient receives the aversive therapy, as needed, to control aggressive, self-injurious, or other harmful behaviors.

Once a GED unit has been activated by the trained staff, a 2 second beep is emitted and an LED light is illuminated on the Stimulus Generator for 2 minutes.

D. Principles of Operation

To initiate a stimulation in order to curb aggressive, self-injurious, or other harmful behaviors, the operator presses the Activate button on the Remote Activator.

When the stimulation is started, the patient receives the stimulation output for a nominal 1.85 seconds. The stimulation signals are generated and transferred to the attached electrodes for stimulating the patient. The activation indicator on the Stimulus Generator remains illuminated for 2 minutes and a message is sent to Remote Activator which then illuminates its Confirm indicator for 2 minutes.

IV. SAFETY FEATURES AND PROCEDURES FOR USE

A. Procedures for Beginning Therapy with Aversive Conditioning Devices

The GED is prescribed for use in patients as an aversive therapy to treat extreme behavior that is harmful to the patient or others. The GED is only used when other therapies to treat the patient have failed. As JRC is often a last resort institution for many patients, many of these therapies have been tried at other institutions. Regardless, upon enrollment at JRC, patients are fully evaluated and a treatment plan consisting of positive behavior therapies and/or medication are started.

Only when these positive therapies are determined to not be adequately controlling a patient's aggressive, self-injurious, or other harmful behaviors is aversive therapy even considered. **Attachment 2** provides a patient summary table of all patients currently at the Center who have been treated with the GED devices. As can be seen from this table, the patients' behaviors are extreme and they have failed treatment with numerous other methods and medications prior to receiving treatment with aversive conditioning. For patients who are currently receiving aversive therapy in addition to other treatments, they have an average of 28.5 months (range: 0-183 months, median: 9 months) of treatment at JRC prior to using the GED devices. The GED devices are used in conjunction with the positive reinforcement behavior modification systems in place at the Center.

Importantly, before the patient may begin treatment with a GED device, the following procedural safety controls must have taken place:

1. Other therapies used to treat the patient have failed;
2. The parent/guardian must provide written informed consent;
3. A doctoral level clinical (*e.g.,* Ph.D.-level licensed psychologist or a Ph.D.-level Board Certified Behavior Analyst) must prepare an appropriate treatment plan prescribing use of the GED device;
4. A peer review committee must review the treatment plan and deem it appropriate;
5. The school district or agency that referred the school-aged patient to JRC also must approve the treatment plan and incorporate it into the patient's Individualized Education or Service Plan;
6. A physician must certify the absence of medical contraindications to the use of GED;
7. A human rights committee must approve the treatment plan; and
8. The patient must be assigned by a Massachusetts Probate and Family Court his or her own court-appointed independent counsel who may hire court-funded experts, as appropriate, to evaluate the patient and oppose the treatment in court, if warranted, and the treatment plan must be authorized by a Massachusetts Probate and Family Court.

In the majority of cases, where a doctoral level clinician determines that other therapies are failing and proceeds with use of the GED device, treatment with the GED-3 is attempted first, prior to using the GED-4A device. In a few instances a patient with very severe self-injury, the GED-4A has been used immediately without starting with the GED-3 device. A clinician may also elect to switch a patient from the GED-3 to the GED-4A as needed, when approved by the court to do so. Note that if a clinician decides to switch a patient from a GED-3 to a GED-4A device, the treating clinician must compose a new treatment plan to submit to the court for approval. Alternatively, the treatment plan may contemplate use of either the GED-3 or GED-4A device in the initial submission to the court.

The following factors are considered when evaluating whether to switch a patient to the GED-4A:

- GED-3 application frequency
- Analysis of trends in GED-3 application frequency
- Efficacy of concurrent treatment (e.g. differential reinforcement, alternative behaviors, pharmaceutical interventions, etc.)
- Overall quality of life of the person receiving the treatment.

Importantly, the use of the GED devices in a patient's treatment plan is within the clinician's discretion and can be stopped at any point in time.

B. Procedures for Activation of GED Stimulator to Curb Harmful, Aggressive or Self-Injurious Behavior

When an operator/therapist observes harmful behaviors that are designated in the patient's treatment plan to receive an aversive stimulus to treat or prevent dangerous or harmful behavior, the operator/therapist must follow these steps:

1. Observe the patient prior to and during the activation. The operator/therapist must be within the audible range of the beeper of the GED Stimulus Generator.
2. Depress the Activate button on the Remote Activator.

When activated by trained treatment center staff, the GED delivers a 2-second electrical stimulation to the patient at the location of the electrode.

C. Patients are Evaluated after Every GED Activation

Each activation of the GED device is documented and, per JRC protocol, each patient is evaluated by a nurse within 24 hours of the treatment being administered. A staff member must visibly check the area of the body on which the electrode is located immediately after administration of the GED therapy. The GED electrodes must be rotated and moved on the body so that they are not in the same skin area at the top of each hour and also immediately after every application. Additionally, the Center and its use of the GED devices, including any complaints related to the devices, is subject to oversight and inspection by Massachusetts' state agencies and their investigation of any complaints and by the courts.

Patients are routinely monitored on a weekly basis for physical and mental well-being as well. Staff are further instructed to carefully monitor any patients receiving aversive therapies for changes in behavior such as increases in aggression, escape behaviors, emotional reactions, sleep difficulties, and any other physical or emotional reaction or change.

D. Documentation of Therapy, Complaints, and Maintenance of Devices

Staff carry a behavior recording sheet for each individual patient with them 24 hours a day / 7 days per week. This sheet is used to record any inappropriate, dangerous, or harmful behaviors of the patient, as well as any interventions administered, including application of the GED.

In addition, each application of the GED is reported to the nursing and monitoring department, and recorded in a separate database. This indicates the location of the application, the reason for the application, any antecedents exhibited as well as all staff present. This data is also downloaded to be reviewed by the clinician.

Devices are calibrated on a regular schedule, where each GED-3A is calibrated at least once every 6 months and each GED-4 is calibrated at least once every 3 months.

Any complaints related to the devices are documented and investigated in accordance with FDA compliant procedures.

V. CLINICAL EXPERIENCE

A. Aversive Therapy in the Literature

The effective use of contingent shock has been reported in peer reviewed published literature for over 50 years and has proven to be a necessary tool in reducing life-threatening self-injurious behavior at JRC for over 20 years.

Salvy et al. noted that "Operant punishment may be critical to treatment success when the variables maintaining problem behavior cannot be identified or controlled (Dura, 1991; Iwata, 1988; Vollmer & Iwata, 1993), or when problem behavior must be suppressed rapidly to prevent serious injury, as it is the case with self-injurious behavior (Linscheid, 1993; Linsheid and Meinhold, 1990; Linscheid, Pejeau, Cohen, & Footo-Lenz, 1994; Matson & DiLorenzo; 1984; Mulick, 1990; Mulick & Kedesdy, 1988; Mulick, Schroeder, & Rohan, 1980, Van Houten, 1983)."[18] The authors noted that they successfully eliminated head banging in a 3-year old girl (using the FDA-cleared SIBIS device) who at the time of referral had a 18 month history of self-injury that occurred over 100 times per day. This treatment was performed through Ohio State University and Columbus Children's Hospital. A 7-month follow- up found that the effectiveness of contingent skin shock ("CSS") was maintained across all settings.

In a three year study conducted by Duker and Seys (2000), the authors evaluated the effectiveness of CSS on the amount of mechanical restraint that was necessary to keep their patients safe.[19] It should be noted that the stimulation device they used was approved by the Dutch, Belgian, and Canadian health authorities.

In the study, eight adults (18 to 44 years old), with severe self-injury, were treated with CSS and they were compared to a matched group of 8 adults that were treated with medication and positive-only behavior modification procedures. The authors found a significant reduction of mechanical restraint in the group treated with CSS as compared to no change in the amount of restraint for the control group. In addition the amount of self-injury also significantly decreased in patients in the CSS group. Over the 8 years that they have been using CCS across 39 individuals they have produced an 82% decrease in self-injury.

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[18] Salvy, S., Mulick, J., Butter, E., Bartlett, R., Linschield, T. Contingent Electric Shock (SIBIS) and a Conditioned Punisher Eliminate Severe Head Banging in a Preschool Child. *Behavioral Interventions*, Vol. 19, 2004

[19] Duker, P.C. & Seys, D.M. (2000). A quasi-experimental study on the effect of electrical aversion treatment on imposed mechanical restraint for severe self-injurious behavior. *Research in Developmental Disabilities, 21,* 235-242.

There is also a great deal of support in the basic and applied literature for the notion that increasing the magnitude of a shock will result in greater reduction in the behavior that the shock is made contingent upon. Lerman and Vorndran note the following in their review on punishment: "The common assumption that a larger magnitude of a given punishment will be more effective than a smaller magnitude is not strongly supported in the current literature, with the exception of findings on contingent shock."[20]

The practice of increasing the magnitude of a contingent skin shock stimulus has been demonstrated in the applied literature. Duker and Seys (2000) noted that skin shock has failed to show long- term effectiveness in other studies because too weak a stimulus was used. "It is, therefore, suggested that employing a relatively strong electrical stimulus to maintain suppression of severe and life-threatening [self injurious behavior] SIB may be necessary."[21] Duker & Seys (1996) noted that one way of coping with apparent adaptation to a skin-shock was to increase the intensity of the stimulus.[22] Williams, Kirkpatrick-Sanchez, and Iwata (1993) demonstrated that switching from a 3.5 mA CSS stimulus to a 18.5 mA stimulus produced immediate and large reduction in self-injury.[23] They also noted the following: "Although the treatment of severe SIB with relatively mild contingent shock is effective for some individual (Linscheid et al., 1990), results of this study demonstrate that a higher level of shock may be required for others."[24]

B. GED Experience in the Literature

As discussed above, the GED device has been in use since 1990 at the Judge Rotenberg Educational Center facilities. A number of articles have been written and published about the use of the GED devices at JRC, as follows. Copies of the following articles are provided in **Attachment 5**.

Side effects of contingent shock treatment
W.M.W.J. van Oorsouw, M.L. Israel, R.E. von Heyn, P.C. Ducker
Research in Developmental Disabilities, 2007

In this study of nine participants (five male, four female; ages ranged from 8 to 30), the use of the GED-1 device was evaluated to determine whether the participants exhibited four side effects once placed on the contingent shock (CS) therapy at JRC. Four specific side effects were evaluated as follows: positive verbal and nonverbal utterances (PVNU), negative verbal and nonverbal utterances (NVNU), socially appropriate behaviors (SAB), and off task behaviors. For all nine participants, CS therapy was viewed as a last resort treatment method because reinforcement procedures and pharmacological treatments were deemed unsuccessful.

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[20] Lerman, D. & Vorndran, C. (2002).On the status of knowledge for using punishment: implications for treating behavior disorders. *Journal of Applied Behavior Analysis, 35***,** 431-464, 442.

[21] Duker and Seys (2000) *supra* at 240.

[22] Duker, P.C. & Seys, D.M. (1996). Long-term use of electrical aversion treatment with self-injurious behavior. *Research in Developmental Disabilities, 17,* 293-301.

[23] Williams, D.E., Kirkpatrick-Sanchez, S., & Iwata, B.A. (1993). A comparison of shock intensity in the treatment of longstanding and severe self-injurious behavior. *Research in Developmental Disabilities, 14*, 207-219.

[24] *Id.* at 215.

The study assessed baseline behavior (i.e. CS treatment was not provided) against CS treated behavior. Participants were video recorded for 10 minutes per day, 5 times a week. Each 10 minute segment was further divided into 10 second intervals, for which observers assigned one of the four target behaviors to characterize the interval.

Data was plotted across a chart for which seven clinicians independently judged the results, determining whether there was a significant change in behavior between baseline and treatment phases of the study.

In all behavior categories (i.e., PVNU, NVNU, SAB, and OT) the study found that participants either significantly improved, or did not show any change, when the treatment phase was compared to baseline, and further, that negative side effects were not observed.

As a limitation, the study noted that because it did not assess cognitive ability of the participants, the participants may not have been capable of showing particular behavior (e.g., SAB). Nor did the study assess behavioral change across the group. Therefore, the study indicated that side effects may differ across individuals.

Treatment of Aggression with Behavioral Programming that Includes Supplementary Contingent Skin-Shock
Matthew L. Israel, Nathan A. Blenkush, Robert E. von Heyn, and Patricia M. Rivera
JOBA-OVTP Volume 1, Number 4 2008

In this retrospective analysis of 60 participants (41 male, 19 female; age ranges from 9 to 36) enrolled at JRC were assessed over a 3-year period were subjected to the GED-1 (52 participants started), GED-4 (8 participants started), or GED-1/GED-4 (two patients switched from GED-1 to GED-4) devices to determine the effectiveness of the contingent-skin shock treatment (CSS). All participants in this study had been rejected by, unsuccessfully treated in, or expelled from settings that had used a combination of positive-only behavioral interventions and psychotropic medications. Topographies (e.g., hitting, biting, kicking) of participants were tallied as each episode occurred 24 hours per day, 7 days per week. Hand counters were used to count high frequency behaviors.

A baseline behavior phase was established for each participant. During this baseline phase, positive programming was used to treat aggressive behavior (e.g., field trips, additional privileges). The length of the baseline phase varied among participants due to the timing for which the patient was court-approved to receive CSS treatment upon entering JRC. The treatment phase of the study added the use of the GED device in addition to the positive programming therapy.

During the baseline phase, the frequency of behaviors was either increasing (accelerating) or flat when CSS was introduced for 40 participants (68% of the 59 cases where there was sufficient information to characterize the trend). In the remaining 19 cases, even though the behavior was decreasing in frequency (decelerating), CSS was introduced because the behavior was too dangerous to be allowed to occur at the frequency presented.

100% of participants reached treatment effectiveness (90% of greater reduction from baseline). Casual inspection of data overall indicated that the GED was effective in decelerating aggression with almost every participant. In 48 cases (80% of the participants), aggressive behaviors were reduced immediately to a zero or near-zero level and remained at that level for whatever time

remained in the 3-year period. In 5 cases, the frequency jumped down and then showed a deceleration, but had not reached zero within the remainder of the 3-year period. In the remaining 7 cases, the level of aggression during the treatment phase was substantially lower than during the baseline and reflected clinically meaningful improvement.

The number of applications of the GED devices was tallied for each patient. The range was from 0 per week to 12.15 per week, over the three year study period. In some cases (n=7), patients did not receive any application at all after the first week. In other cases (n=10), patients received only 1 or 2 applications after the first week.

Although indicated as requiring further research, the study found only one negative side effect, temporary discoloration of the skin that cleared up in a few minutes or days. Participants, at times, may have shown temporary emotional behaviors, a temporary tensing of the body, or attempted to remove the device or grab the transmitter. Such behaviors were classified as “immediate collateral behavior” and not side effects.

Finally, the study noted several positive side effects from CSS treatment, including participants being able to succeed in the classroom and having a more positive outlook on the future. The study indicated that this should be further researched.

Seven Case Studies of Individuals Expelled from Positive Only Programs
Matthew L. Israel, Nathan A. Blenkush, Robert E. von Heyn, Christine C. Sands
JOBA-OVTP Volume 2, Number 1, 2010

Seven patient histories were reviewed and summarized. In all seven cases, individuals with severe behavior problems were expelled from positive reinforcement only institutions when their behaviors become too difficult to handle. All seven patients were subsequently admitted to the Judge Rotenberg Educational Center and treated with the GED device in addition to positive-only treatment to curb their identified problematic behaviors. When skin shock was added to their treatment programs, all seven patients made significant academic and social progress, providing support for the use of supplemental aversive when positive-only interventions have failed and the individuals are at continued risk of harming themselves or others.

C. Daily Experience

Since use of the GED Device began at JRC in 1990, the Center has utilized defined procedures in the treatment of each patient with the device.

Every patient is evaluated at the time of entry to JRC and they are thoroughly evaluated to determine an appropriate treatment plan. The patient’s self-destructive, violent, and other problematic behaviors are evaluated by JRC. The frequency of these behaviors is recorded on a daily recording sheet that has been designed by the doctoral level clinician overseeing the patient. The data are entered on the patient’s chart each day. Positive-only procedures, such as counseling, differential reinforcement, contracting etc. are used before the GED is employed in a patient’s treatment regimen, as needed. If these treatments are unsuccessful, treatment with the GED devices may be initiated. On average, patients are treated at JRC for 28.5 months (range: 0-183 months, median: 9 months) through various methods before considering that these therapies are not adequately controlling the dangerous behaviors. Of the 241 patients currently enrolled at JRC, 71

patients are indicated for use of aversive therapy and only 60 patients are currently utilizing GED devices.

The occurrence of the defined problematic behaviors is trended over time to reflect changes in treatment therapies. Samples of these trending charts are provided in **Attachment 3**. As can be seen by an informal review of these data, each patient's diagnosed self-destructive and violent behavior lessened substantially while undergoing treatment with the GED device. The Center believes that these data are fully supportive of the clinical efficacy of the device.

Importantly, the typical patient treated with the aversive conditioning devices receives limited exposure to the stimulus delivered by the device. A full accounting of all patients who have been treated with the GED device is provided in **Attachment 2,** describing the aggressive and self-injurious behaviors they consistently exhibited, the previous treatments they have tried, and the average number of stimulus they have received with the GED device over the past 6 months.

As described in Section IV.D., patients are evaluated every time a shock is administered. Additionally, patients undergo weekly routine physical and mental health evaluations by attending clinicians. JRC has not found any side effects associated with aversive conditioning except the occasional discoloration of the skin that disappears within an hour to a few days and some brief, temporary anxiety just prior to the delivery of the application. There was one reported instance in 2010 of a burn that may have been caused by the GED. The Center performed a thorough investigation and physical evaluation and concluded that the injury was not a burn related to the GED device as the patient had not received a GED stimulus anytime in the past 7 days. No long term side effects have been noted either. However there are significant positive side effects that can be summarized as an improved quality of life. Patients are generally free of restraint and psychotropic medications and free of injuries. They have access to the community and are actively learning educational, vocational and habilitative skills. In a number of cases, treatment with the GED has allowed the patient to undergo treatment of other medical conditions that was not previously possible due to extreme self-injurious behavior.

In the history of the Center, all patients who have been treated with the GED devices have experienced a decrease in their aggressive, self-injurious, or other harmful behaviors when receiving therapy with the device. Additionally, the device has allowed numerous patients the opportunity to learn to control their behaviors and to entirely stop using the device as a form of treatment. Specifically, of the 241 current patients at the Center, 23 patients have been successfully transitioned from aversive therapy and do not currently require the GED device to control the self-injurious, aggressive and harmful behaviors which originally prompted the therapy. Twelve (12) of these patients have been off the device for a sufficient amount of time that their treatment plans no longer even include an indication for aversive therapy. Information on these patients who have been successfully treated with aversive therapy is included in the patient summary table provided in **Attachment 2**.

VI. BANNING AVERSIVE THERAPY PRESENTS SIGNIFICANT SAFETY RISKS

Considering the severity of the disabilities of each specific patient who is currently utilizing the device, banning the use of aversive conditioning devices would likely cause these patients to suffer irreparable harm including the likely reoccurrence of their violent and self-mutilating behaviors that are currently being successfully treated with the GED device. Descriptions of these dangerous

behaviors in which these patients frequently engaged prior to their treatment with the GED device, along with descriptions of all of the treatments that were tried and failed to successfully treat the behaviors, including massive dosages of medication, are documented in the patient records, available at JRC, and summarized in **Attachment 2**. These patients were treated with all available forms of treatment at psychiatric hospitals and many other types of residential treatment programs prior to their placement at JRC and these facilities could not effectively treat the behaviors or keep the patient safe.

Attachment 4 provides a letter from a consulting physician, Dr. Edward Sassaman, regarding the potential consequences that would result from the removal of the GED from a patient's treatment plan. Dr. Sassaman's *curriculum vitae* is also provided in **Attachment 4**.

As noted by Dr. Sassaman, without use of the GED, alternatives for these patients to control the undesirable and often dangerous behaviors would likely be limited to (1) a regimen of psychotropic drugs or (2) physical, mechanical, and chemical restraints. Medication and/or restraint will not treat the patients' behavior disorders and will not allow them to be educated and develop skills. Rather, such treatment protocols will simply sedate the patient and cause very harmful side effects.

Notably, these patients have all previously failed therapy with the only available options prior to beginning treatment with aversive conditioning devices. Banning such devices would leave these patients with ineffective or unsafe treatment methods.

Therapy with a cocktail of psychotropic medications would render the patients in a semi-comatose state where they would be sedated, incommunicative and requiring constant care for daily life activities including feeding. It was the effect or failure of these drugs and other treatment regimens which led physicians and parents to refer these patients to JRC in the first place, and for treating clinicians at JRC to elect to use the GED devices in the treatment of these patients. As discussed above in Section II, the side effects of antipsychotic medications, can include, for example, major weight gain, severe sedation, acute and chronic extrapyramidal syndromes (e.g. tardive dyskinesia, akathisia, dystonia, parkinsonism), neuroleptic malignant syndrome, sexual dysfunction, prolactin elevation, sudden cardiac death, nocturnal enuresis, addiction, increased likelihood of diabetes, and/or life-shortening metabolic changes. Moreover, the side effects related to the use of drug therapies are severe as opposed to the side effects associated with the use of the GED which are minimal or non-existent. As detailed in an article comparing the risk-benefit analysis of antipsychotic medication and contingent skin shock for the treatment of destructive behaviors by Nathan A. Blenkush, Director of Research at JRC (**Attachment 5**), the side effects of antipsychotic medications are more numerous and severe than those associated with Contingent Skin Shock.

The other possible alternative to the GED or drug regimen is the use of physical restraints. However, use of such treatment could have serious psychological and physical effects and has led to death in other facilities. However, the use of restraints is strongly cautioned against by federal agencies due to the dangers posed.

In contrast to these other therapies, the GED devices allow patients to learn productive behaviors to replace their dangerous behaviors, perform daily life tasks and interact with others, allowing for their continued education, training, development, and therapy. The GED device does not have the harmful side effects of drugs or restraints.

Any action by the agency that would precipitously remove or require the eventual removal of the GED from the patients who currently rely on this court-ordered therapy would have dire consequences from a patient safety and health perspective. To this end, the patient's behavioral disabilities, and the pain and physical and emotional harm to the patient caused by them, have also been described on numerous occasions by the parents of these patients, and by the patients themselves, at court hearings, legislative hearings, and to the media. The parents and patients have also described all of the other treatments that were tried and were not successful in stopping the dangerous behaviors. They have described the unprecedented and formerly impossible educational progress and community integration their children have been able to accomplish at JRC once their dangerous and disruptive behaviors were successfully treated with the GED device.

The GED device is the only treatment available to these patients to keep them safe, healthy, and allow them to achieve academic progress and independence. Removing these patients access to the GED device could return them to their self-destructive behaviors, seclusion and constant physical, mechanical and chemical restraint, as the only means to attempt to stop them from killing or maiming themselves and physically hurting others. Removal also will likely end the significant educational and behavioral progress they have made at JRC and this loss of progress could be permanent and is considered irreparable harm by law. The prior treatment records and judicial findings concerning these patients prove conclusively that the massive dosages of medication, restraint and other intrusive interventions used with them prior to their treatment with the GED device, failed to stop them from causing severe pain and physical damage to themselves, and, in many cases, caused them to suffer painful and permanent side-effects such as the devastating side-effects of anti-psychotic medication identified above. The prior treatment records also demonstrate that drugs and restraint will not stop these patients from engaging in their dangerous behaviors so they will still cause severe pain and harm to themselves in addition to receiving these ineffective and intrusive alternative treatments.

The GED treatment causes a rapid deceleration of these patients' dangerous and disruptive behaviors down to zero or near-zero levels and on average the patient receives less than two (two second) GED applications per week. JRC's educational program teaches these patients to replace their problematic behaviors with positive behaviors such as social, recreational, and educational activities. There is no doubt that the loss of this highly effective and safe treatment will cause devastating and permanent harm to these patients.

In light of the safety and efficacy information presented above, there is no credible definitive evidence that aversive conditioning devices such as the GED present an unreasonable risk of injury to patients when used in accordance with their treatment plans. To the contrary, given the effectiveness of treatment with these devices, and the lack of treatment alternatives for this limited group of patients with severe aggressive, self-injurious, or other harmful behaviors, the Center believes that banning aversive conditioning devices would actually cause an unreasonable risk of injury to these patients.

Attachment 1

Statement from FDA that the GED products are exempt from 510(k) requirements

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

FEB 2 2 2000

FDA

February 14, 2000

Dr. Matthew Israel, President
Judge Rotenberg Center
240 Turnpike St.
Canton, MA 02021-2341

Dear Dr. Israel:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises from January 31 – February 1, 3 & 10, 2000 at 240 Turnpike St., Canton, MA by the U. S. Food and Drug Administration (FDA).

This report is being provided to you for information purposes. This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any information under FOIA.

If you have any questions, please feel free to contact Domenic Veneziano, Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180, at (781)279-1675 ext. 144.

Sincerely,

Gail T. Costello
Acting District Director
New England District Office

Enclosure
FMD00-065

Judge Rotenberg Center
240 Turnpike St
Canton, MA. 02021-2341
CFN: 1222743 FEI: 1000120805

1/31/99 2/1, 3 & 10/00
LMD

Reason for Inspection

This inspection of the Judge Rotenberg Center in Canton, MA. was conducted as the result of consumer complaint number NEW-2042, attathment #1. The complaint alleges that the Graduated Electronic Decelerator (GED) and GED 4 are not reliable for use. It also alleges that when the devices are reported as malfunctioning, they are not properly tested and are sent back to be used again. The inspection was conducted in accordance with CP 82845B, Inspection of Medical Devices and 81010 Medical Device Reporting. It is FACTS assignment #66008.

History of Business

The Judge Rotenberg Center, formerly known as Behavioral Research Institute (BRI) is located in Canton, Massachusetts. The facility was previously located in Providence, Rhode Island. The Judge Rotenberg Center (JRC) continues to operate day and residential programming tracks for children and adults with behavior problems, including conduct disorders, emotional problems, head injuries, autism and developmental disabilities, (see exhibits #1-3 for center literature). There are one hundred and two students enrolled in the program. Dr. Matthew Israel remains the President and Executive Director of the firm.

Summary of Findings

On January 31, 2000 I visited the Judge Rotenberg Center located at 240 Turnpike St., Canton, MA. Credentials were displayed and an FDA 482 notice of inspection was issued to Ms. Ann Marie Iasimone (see attachment #2). Ms. Iasimone stated that she is the Assistant Director and the most responsible person of the firm at the time of my visit. It was explained that Dr. Matthew Israel who is the President and Director of the firm was in a meeting and would not be available. Dr. Israel was not present throughout the inspection. Ms. Iasimone introduced me to Mr. Robert Duquette, Assistant to Director for Human Resources. Mr. Duquette was present for the entire inspection.

Also present during the inspection were Mr. Jerry Kutcher, Electronics Consultant, Mr. Mike Corrigan, Electronics Consultant and Mr. George J. Wallace, the firm's attorney. These three individuals provided the majority of information contained in this report.

The center uses devices that deliver electro shocks to patients as part of the overall behavior modification program. There are currently three types of devices being utilized by the center on approximately 35 students. Those devices are the GED1, GED3a and the GED4. These units are manufactured at the center and are used exclusively by the center. The center currently has one approved 510(k) for the GED1, K911820. It was explained that the GED3a is an enhancement of the GED1. There are currently ten GED3a devices manufactured to date. The GED3a is being used on four students.

Judge Rotenberg Center
240 Turnpike St
Canton, MA. 02021-2341
CFN: 1222743 FEI: 1000120805

1/31/99 2/1, 3 & 10/00
LMD

The GED4 is another device that was manufactured and first utilized in 1992. Dr.Von hyne is a clinical psychologist who supervises the overall program for students in his caseload. He stated that there are six students currently using the GED4 device. He believes that there were approximately forty units manufactured to date. He explained that the differences between the GED and the GED4 are that the GED4 output is 45 RMS while the GED output is 15 RMS. Also the GED 4 utilizes two 12V batteries. The GED4 is currently being used on six students. No specific submissions with respect to the GED3a or the GED 4 have been made.

It was explained that each patient is a ward of the court and has a court appointed guardian, a court appointed monitor who is a psychologist, a court appointed neurologist and a court appointed attorney. Both the court and the Massachusetts Department of Mental Retardation are aware of and have approved the treatment plans provided for each student.

After discussions with NEW-DO compliance branch and CDRH, it was determined that the firm is exempt form 510(k) notices, and the device is considered to be within the practice of medicine. (See attachment #3).

I was instructed to close the inspection and not to issue an FDA 483.

When I returned to the firm, on 2/10/00 Dr. Matthew Israel was present for the close out via telephone, as well as George Wallace the firm's attorney. Also present were Robert Duquette, Director of Human Resources, Ann-Marie Iasimone, Assistant Director, Jerry Kutcher, Consultant and Glenda Crookes, Director of Residents and Student Services. I explained that it was determined that the firm was exempt under 807.65(d), and I would not be issuing an FDA 483. However, deficiencies were discussed throughout the inspection and the firm asked if I would go over those deficiencies with them. I agreed to do so and relayed the following to them: Deficiencies found at the firm included; lack of device history records, incomplete device master records, incomplete failure investigations and the lack calibration schedules for devices that are to be calibrated every 90 days.

I thanked Dr. Israel and his employees for their time, and the inspection was closed. The firm promised to work on the deficiencies noted above.

Attachments

#1 Complaint NEW-2042
#2 FDA 482 Notice of Inspection
#3 E-mail from Compliance RE: JRC

Exhibits

#1 - #3 Judge Rotenberg Center Literature

Lynne M Dwyer

Lynne M. Dwyer
NEW-DO Inspector

Attachment 2

Summary of patients treated with GED Devices

Utilization of GED Devices for Patients Currently Enrolled at JRC

Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
LA	25	M	MA	Autistic Disorder, Profound mental retardation	Extreme aggression (punching, kicking screaming), self injury (biting self and head banging)	Special education, psychology, occupational and speech therapy, recreational therapy, nursing and psychiatry	Cognitive Development Center,	41	Patient no longer requires aversive therapy with GED device		
DB	21	M	NY	mental retardation with severe cognitive defects	Physical aggression towards others (i.e. bite others, punch others, hit others, kick others, forcibly push others) to include attempts, spit at others.	Keppra (3) 250 mg 2x/day, Risperdal 1mg 3x/day, and Proprandol 20 mg TID Concerta, Seroquel and Adderall XR 10mg	Bronx Lebanon Hospital	9	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
NB	28	M	NY	Autistic, severe mental retardation	hitting, grabbing, biting others, throwing objects, property destruction, noncompliance, spitting on himself and others, smearing/throwing feces, inappropriate urination/defecation, public masturbation, inappropriate sexual touching of others, disrobing in public	Risperdal, Artane, Vistaril, Ritalin	New England Center for Children	4	2	2.17	0-5
DB	38	M	MA	Autism, mental retardation	Aggression (attacking others), health dangerous behaviors (head banging), property destruction (breaking plate glass window)	Mellaril, Haldol, Inderal, Valium	Kennedy Center for Developmental Disabilities, Shield of David Institute, Bronx Developmental Center	3	0	0.17	0-1
PB	48	M	MA	Autism, mental retardation	frequent, violent temper tantrums, self-abusive behavior (biting lip and scratching self, hitting self, picking or forcefully rubbing self, eating inedibles), inappropriate urination and defecation, minimal educational progress, aggression (attacking and grabbing others), property destruction (throwing and tearing objects)	Dexedrine	Tri-City Mental Health Center, Glen Hill Nursery School, Children's Own School, Lakeside School,	158	7	7.61	0-16

** Patients highlighted in green no longer require aversive therapy to control their harmful behaviors*

Utilization of GED Devices for Patients Currently Enrolled at JRC

Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
JC	50	M	MA	Autism, mental retardation	Aggression (hitting, kicking, scratching, pinching, punching, pulling others' hair, gouging, grabbing, pushing, spitting), health dangerous behaviors (biting self, scratch self, each inedibles, rectal gouging, picking skin with fingernails,	Ritalin Mellaril, Haldol	South Shore Mental Health Center, Dally's Nursery School, Lakeside School, Braintree Mini-School, Spear Education Center,	183	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
MC	26	M	MA	Autism, Bi-Polar, mental retardation	Slapping face, eating inedibles, biting and hitting self, rocking forcefully, manipulating genital area	Zoloft, Ritalin, Risperdal, Depakote, Topiramate, Geodon, Congentin, Haldol, Clonidine	League School (Walpole, MA), New England Medical Center, Floating Hospital for Children, Franciscan Children's Hospital Inpatient Program for Children with Developmental Disabilities and Psychiatric Disorders	6	Patient no longer requires aversive therapy with GED device		
JC	44	F	NY	Autism, mental retardation	pulling out clumps of hair, banging head on objects, picking at skin until bleeding	Ritalin, Mellaril (200mg)	Lifeline, Queens autistic program, Queens Psychiatric Center	121	2	2.61	0-8
AC	27	M	NY	Autism, pervasive developmental disorders, mental retardation	Self injury (head banging, scratching self, inducing vomiting, inappropriate urination/defecation, smearing vomit and feces), noncompliance, property destruction (clearing tables, knocking over furniture), disruptiveness (screaming, tantrums), inappropriate sexual behavior (rubbing self against women's legs, attempting to sit on women's laps and touch their breasts, rubbing against staff and peers from behind), aggressive behavior (biting, hitting, kicking, scratching, pinching)	Restraints, Wellbutrin, Risperdal, Depakote, Thorazine, Zyprexa, Lithium, Zoloft, Seroquel	Anderson School	7	0	0.33	0-4

** Patients highlighted in green no longer require aversive therapy to control their harmful behaviors*

Utilization of GED Devices for Patients Currently Enrolled at JRC

Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
EC	27	F	NY	Autism, mental retardation	severe aggression, self injury, noncompliance	Restraints, Lamictal, Thorazine, Lithium, Abilify, Concerta, Depakote, Tegretol, Cogentin, Aricept, Atarax, Risperdal	Public School 77K, The League school	37	1	0.89	0-4
PD	54	M	CT	autism, mental retardation	Physical aggression i.e. hit others, scratch others, pinch others, grab others, bite others. Bite self to cause marks or injury, scratch self to cause injury, hit or bang chin.	Valium Haldol, Cogentin, Mellaril,	Benhaven, Montanari School, Ohara Walsh School, Ives School, Yale Child Study Center	83	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
LD	43	M	MA	pervasive developmental disorders, mental retardation	gagging and poking self, bouncing forcefully on toilet, touching, manipulating, and kissing objects, biting, kicking, grabbing and head butting others, gagging himself, head bagning, screaming and yelling, repetitive statements and noises	Psychotropic medications, timeout, redirection, stimulus control procedures, specially designed workplace, dense schedules of reinforcement, withholding reinforcement following negative behaviors, physical restraints	Baldpate Hospital, The League School, Shore Educational Collaborative, New England Center for Autism, the May Institue	1	0	0.5	0-2
MD	29	M	NY	pervasive developmental disorders, mental retardation	aggression (biting, pulling hair), self injury (biting self and slapping self), property destruction,	various forms of psychotropic medication (Thorazone, PRN, Haldol, Klonopin, Zyprexa, Dexedrine, Orap, Risperdal, Depakote, Clonidine, Cogentin, Benadryl, Zoloft, Luvox) and therapy	Suffolk Child Development Center, The Mary Haven School, Kramer Center, Bellevue Hospital, Anderson School, St. Francis Hospital (Psychiatric Unit)	4	0	0.5	0-2

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Utilization of GED Devices for Patients Currently Enrolled at JRC

Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
AE	32	M	VA	Bi-Polar, Mild mental retardation	punching, head butting and biting others, hurting self, biting and hitting self, stabbing self, picking scabs and open wounds, faking seizures, destroying property and throwing objects, screaming and yelling, refusing to following directions	Zoloft, Haldol, Risperdal, Congentin, Ativan, Depakote, Zyprexa, Seroquel; group therapy	Dominion Hospital, DeJarnette Center, Wood Services, Cabiniss Consultants, Virginia Baptist Hospital, Wall Enterprises (2 days), Northern Virginia Training Center, Fairfax County Adult Detention Center	22	0	0	0
ME	31	M	NY	Moderate mental retardation Autism	extreme agitation, aggression (hitting, biting, pushing others), major disruptive behavior (masturbating in public, playing with salvia, loud noises), self injury (picking gums, biting self, running away, forceful body rocking)	Mellaril, Thorazine, Depakote, Risperdal	Saint Vincent's Hospital	3	1	1.5	0-8
TE	27	M	NY	Autism, mental retardation	aggression (hitting, pushing, kicking), self injury (hitting, biting, banging), property destruction	Mellaril, Imipramine, Clonidine		3	0	0.17	0-2
LE	23	F	MA	Schizoaffective d/o, pervasive developmental disorders, Reactive Attachment d/o, Mild mental retardation	head banging, induced vomiting, biting lip until bleeding, slamming face into floor until bleeding, knee problems requiring surgery due to banging into ground	Thorazine, Trilafon, Abilify, Haldol, Zyprexa, Risperdal, Clozaril, Lexapro, Prozac, Zoloft, Luvox, Valium, Klonopin, Ativan, Topomax, Clonidine, Lithium, Depakote, Lamictal, Inderal, Tegretol, Atarax, Ritalin, Adderall, Cogentin, Valium	The Protestant Guild, The Kolburne School, The Latham School, Community Therapeutic Center	7	0	0.17	0-2

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Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
EF	51	M	MA	Autism, mental retardation, intermittent explosive	Physical aggression (e.g. hit others, kick others, scratch others, pinch others, bite others, punch others, pull hair, gouge others, grab others, push others), aggressive posturing (punching fist into palm, raising fist to people).	thorazine, haldol, lithium, librium and mellaril	League School, New England Medical Center, Avalon School, Fine House, Lindemann Mental Health Center	91	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
DF	29	M	NY	traumatic brain injury, ADHD, Mild mental retardation	health dangerous behaviors, aggression, major disruptive behaviors	Thorazine, Ritalin, Clonidine, Klonopin, Buspar, Tegretol, Zyprexa, Dexedrine, Lithobid, Haloperidol	Developmental Disabilities Institute, Brook Haven Career Institute, Devereux School	4	Patient no longer requires aversive therapy with GED device		
EG	29	F	MA	mental retardation Tuberous Sclerosis	Self-induced vomiting, seriously injuring staff members and caretakers, noncompliance, loud outbursts, inappropriate urination/defecation, head banging, property destruction, biting self, pulling hair, ripping at skin, tearing clothes, throwing objects, temper tantrums, rubbing face on floor carpeting	Restraints; Tegretol (seizure control), Zantact, Propulsid, Clonidine, Ritalin, Pamelor, Clonazepam, Dilantin, Risperdal, Prozac, Anafranil, Thorazine, Lithium Carbonate, Stelazine, Paxil, Mellaril, Pindolol	DR. W.J. Creel Elementary School, Trainable Mentally Handicapped Program at Lockmar, Palm Bay Elementary, Fruitland Park Learning Center (Polk County Public School), Mary Strang Children's Treatment Unit, Stambaugh Middle School Day Program, Winter Haven Hospital, Florida Institute for Neurological Rehabilitation, Sun Coast-New Options Program	2	1	1.89	0-8

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Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
AG	33	M	ma	Moderate mental retardation ADHD, Seizure disorder	Aggression, property destruction, health dangerous behaviors, non compliance, self injury	Dilantin, Tegretol, Neurontin, Thorazine, Luvox, Ativan, Phenobarbital, Depakote, Haldol, Clonidine, Trazodine, Risperdal	CHARMSS Collaborative; Crotched Mountain Rehabilitation Center, Arbour Fuller	9	0	0.56	0-6
AG	19	M	NY	Severe mental retardation, Autism, pervasive developmental disorders	aggression, grabbing others, slapping face, throw self to floor, placing inedibles in the mouth, pressurize ears, leave supervised area, inappropriate urination/defecation, noncompliance	Thorazine		6	7.5	9.94	0- 40
AG	21	F	NY	Autism, mental retardation Seizure disorder	spitting, smearing saliva, pushing, hitting, scratching, pinching and grabbing others, pulling others' hair, throwing and banging objects, clearing off tables, slapping her head, pulling her hair, biting herself, smearing feces, eating inedible items, yelling and screaming	specialized educational and habilitation services (speech therapy, physical therapy, occupational therapy, specialized educational curriculum, ADL, in-home case services)	St. Frances School for the Deaf, Brooklyn School for Special Children, Cooper Street School, Queens School, Marathon School	14	2	2.33	0-8
SH	44	F	MA	mental retardation, pervasive developmental disorders, NOS	assaultive behavior (hitting, pushing, grabbing, biting, kicking), property destruction, self injury (pica, self-biting, head banging, scratching and pinching self, hoarding and placing small items in body orifices)	Psychotherapy, Haldol, Lithium, Mallaril, Prozac, Depakote, Risperdal, Congentin	Alternatives, Inc., A.E.I. Work Center, Riverside Community Care, Arbour Fuller	27	1	1.44	0-7
JH	24	M	MA	pervasive developmental disorders, Impulse Control Disorder	yell loudly, throw objects, hit peers, urinate inappropriately, aggression, inappropriate sexual behavior, exposing his genitals, biting others	Cogentin, Inderal, Depakote, Abilify, Topamax, Lithium, Thorazine restraint was ineffective differential reinforcement contracts	Head Start, The Lee School, Arbor Hospital, Protestant Guild for Human Services	12	2	1.83	0-8

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LJ	27	F	NY	Intermittent explosive d/o, Psychosis NOS, Mild mental retardation	severe aggression, self injury	restraints, various psychiatric medications	South Oaks	N//A	0	0	0
TJ	24	M	NY	Oppositional defiant disorder, pervasive developmental disorders, moderate mental retardation	Physical aggression towards others (i.e. hit others, kick others, grab others, choke others, stab others with objects, etc.), attempts to physically aggress, aggressive posturing, spit at others, verbal threats of aggression	Thorazine, Haldol and Neurontin, Cogentin	Devereux, Bronx Children's Hospital, Westchester Medical Center	11	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
DK	27	F	MA	Mild mental retardation, mood disorder	Aggression, health dangerous behaviors, property destruction, impulsive behaviors	Luvox, Olanzapine, Seraquel, Thorazine, Moban, Topomax, Trilaphon, Trileptal, Ritalin, Lamictal, Depakote, Zarontin, Neurontin	Shore Collaborative, Seem Collaborative, Franciscan's Children's Hospital, Hunt Center, Carney Hospital, Learning Center (Walthan, MA), Devereaux Residential Program, Protestant Guild	2	0	0.94	0-5
LL	31	M	MA	Asperger's Disorder, pervasive developmental disorders	Aggression toward staff (hitting, kicking, grabbing, biting, pulling hair)	Depakote, Risperdal, Seroquel, Zyprexa, Tegretol, Zoloft, Klonopin, Ativan, Clonidine	Walker Day School Program, League Day School Program, Somerville's Adolescent Psychiatric Inpatient Unit	4	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		

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AL	27	F	NY	Autism, Personality Changes due to Viral Meningitis, Aggressive type severe mental retardation, Arnold Chiari Malformation	High frequency of aggression, property destruction, major disruptive behavior	Topamax, Cogentin, Neurontin, Risperdal, Seroquel, Thorazine, Mellaril	Hungerford Program, New Dorp High School, St. Vincent's Psychiatric Adolescent Unit	7	0.5	0.83	0-4
CL	22	M	NY	pervasive developmental disorders, Autistic, ADHD	hyperactivity, aggression, disruption, noncompliance, self injury	Ritalin, Tenex, Risperdal, Clonidine, Deptakote	ABA Program, Herbert G. Birch School	9	0	0.89	0-5
EL	22	M	NY	Autism		Metadate, Zyprexa, Risperdal, Thorazine		17	0	0.33	0-4
JL	21	M	MA	mental retardation, Autism, developmental disabilities	aggression, hyperactivity self injury	Depakote 1500 mg, Abilify 30mg, Lexapro, Straterra and Ritalin	Bandbain Behavioral School, Pauladin School, Victory School, ARC of Brownwood, Princeton Charter, ACE Academy, CASH Program	7	0	0.39	0-2
TL	22	M	NY	Mental Retardation, Autism, ADHD	aggression, pica, property destruction, hit/slaps self, induction of vomiting, noncompliance	Thioridizine, Risperdal, Ritalin	Schneider Children's Hospital	9	0	0	0
GM	50	M	CT	Schizoeffective disorder, Borderline Personality disorder	swallowed pencils, toothbrushes, chess pieces leading to perforated esophagus, biting himself, eye gouging leading to limited vision, ripped his scrotum, threats of self injury and suicide	Electroconvulsive therapy, restraints, 10 antipsychotic medications, 5 anti-anxiety medications, 5 antidepressants, 4 anticonvulsants, 2 mood stabilizers, beta blocker	Whiting Forensic, hospitalized 28 times in psychiatric settings	0	Patient no longer requires therapy with GED device		
GM	50	M	CT	Schizoeffective disorder, Borderline Personality disorder	swallowed pencils, toothbrushes, chess pieces leading to perforated esophagus, biting himself, eye gouging leading to limited vision, ripped his scrotum, threats of self injury and suicide	Electroconvulsive therapy, restraints, 10 antipsychotic medications, 5 anti-anxiety medications, 5 antidepressants, 4 anticonvulsants, 2 mood stabilizers, beta blocker	Whiting Forensic, hospitalized 28 times in psychiatric settings	0	0	0	0

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CM	48	M	MA	Autism, Mental Retardation	Pinching, biting, hitting, kicking others, pulling others' hair, head-butting others, grabbing other, picking at cuts and scabs, poking own eye with finger or other object, picking at gums, scratching self forcefully	Thorazine, Ritalin, Valium, Benadryl	Tidewater, Onslow County ARC, Old Dominion University Exceptional Child Center, Woods School, Devereux	119	4	5.28	0-11
NM	28	F	MA	Landau-Kleffner Syndrome	Hit, punch, and pinch own face, head bang, drop self to floor, physical aggression toward others (pinching, hitting, head-butting, scratching)	Depakote sprinkes-875mg/day, Risperdome, Buspar, Prednisone	May Institute, University of Nebraska Medical Center, Franciscan Childrens Day Program, Perkins	13	0	0	0
WM	32	M	NY	Mental Retardation, Autism	Pushing, hitting, banging and hitting own head, mouthing objects, biting hands, property destruction, throwing objects, inappropriate masturbation, inappropriate sexual touching, forcefully grab others, eat feces, smear feces, pick nose to cause bleeding, forcefully grab own groin, put inedible objects in mouth, lick inedible objects, lick people, inappropriate urination/defecation, yelling, screaming, put face in other people's food, hands in pants, holding or fondling penis while sitting on toilet, noncompliance	Risperdal, Buspar, Xanax, Risperdal, Clonidine	AHRC Children's Education Center, Berkshire Meadows, AHRC, Little Village School	16	4	4.61	0-10
WM	52	M	MA	Autism, Mental Retardation	set kitchen on fire, attacks on peers, routinely broke windows at institution, destruction of property	Haldol, Thorazine, Benadryl Lithium restraints	Wretham State School, Association for Mentally Ill Children	124	1	0.94	0-4
RM	26	M	MA	Autism, Mental Retardation	rip/tear clothing, hit self, refused to sit on moving vehicle, bite others, kick others, grab others forcefully, scratch others, slap others, head-butt others, grab staff face and push against the wall	Clonidine, Clomipromie, Topomax, Lithium, Seroquel, Risperdal, Neurontin	League School, Language and Cognitive Development Center, Hogan	5	5	6.61	0-15

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MM	39	M	MA	Autistic Disorder, mental retardation (Moderate to severe), Bipolar disorder (mixed type), & Landau Kleffner Syndrome (Seizure Disorder)	attacking others, inappropriate urination, masturbation, inappropriate touching of peers and staff, stripping, pulling other's hair, hitting and biting self	time-out, isolation, restraint Mellaril	Solom Carter Fuller School, Little People's School, Ohrenberger School, New England Center for Autism	2	1	1.83	0-5
AN	27	M	NY	Autistic Disorder, mental retardation (Moderate to severe)	hitting, biting, head banging, running away, stealing food	Depakote, Seroquel, Lithium, Haldol, Ativan	Child Psychiatry Inpatient Unit at Long Island Jewish Medical Center	5	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
EN	43	M	NY	Atypical Psychosis, mental retardation	throwing chairs, chewing on window sills, biting himself, running away, attaching staff	thorazine, one-to-one staffing	Mishkon, Adolescent Autistic Day Program	17	0	0.61	0-5
AO	32	M	DE	Mental Retardation, Autism	attacks on others; breaking windows and doors, biting, kicking hitting	physical and mechanical restraint Abilify, Seroquel, Depakote, Prozac, Ativan, Risperdal, Paxil, Propranolol, Imipramine, Buspar	Delaware Autism Program, Bancroft School	2	4	4.67	0-12
MP	29	M	NY	Asperger's Disorder, Obsessive Compulsive Features, R/O Major Depressive Disorder, Recurrent Moderate	aggressive, ritualistic behavrios, head banging, picking at skin until bleeding, biting	physical restraint, helmet for head banging	First Step, The Child School, Pathway Residential School, Robert Jolicoeur Adolescent and Educational Services,	6	Patient no longer requires aversive therapy with GED device		

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SP	32	M	NY	Autistic D/O, R/O Bipolar Affective D/O. Profound mental retardation, Bilateral hearing impairment, with surgical obliteration of R-ear and profound hearing deficit in L-ear; repetitive soft tissue damage to R-temple w/self-induced trauma	self-injury requiring restraints, head banging, sexually touching others, masturbating at inappropriate times, screaming, hitting others and himself	Risperdal, Klonopin, Luvox, Ritalin, Pondimin	Devereux Kanner Center	4	1	1	0-5
DP	44	M	MA	Mental Retardation, Autism	self-induced vomiting, self-abuse, gagging, masturbating at inappropriate times, smearing feces, squeezing his genitals and buttocks, rectal gouging, putting his hands down his throat and scratching tissue, scratching gums	Ritalin, Thorazine, Mellaril, Haldol, Noctec	Michael Reese Center, Cupertino School, Ezperenza School, Fox School, Cupertino Center, St. John's Developmental Center, Devereaux School, Kennedy Center in Baltimore (now Kennedy-Krieger Institute)	29	0	0.17	0-2
AP	22	M	MA	Pervasive Development Disorder NOS	aggression, self-injury, head banging, chronic biting, rectal gouging, face slapping, head butting	Aripiprazole, Sertaline, Buspirone, Trazodone, Chlorpromazine, Tranexe	May Institute	56	0	0.28	0-2

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RP	39	m	DE	Intermittent Explosive d/o, Autism, Mild/Mod mental retardation History of Neuroleptic Malignant Syndrome	attacks on staff and parents, smear feces, urinate on wall, kicking and biting others, head banging, running away	mechanical and chemical restraint Tegretol, Serentil, Topamax, Ritalin, Mellaril, Ativan, Cogentin, Depakote, Hladol, Neurontin, Prozax, Risperdal, Abilify, Inderal, Zyprexa, Clozaril	Little Red School House, Staunton Psychiatric Hospital, Eastern State Psychiatric Center, Georgia Regional Hospital, Central State Hospital, Winnebago Mental Health Institute, Southern Wisconsin Mental Retardation facility, Bancroft NeuroHealth's Intensive Residential Program New Jersey, Ancora Psychiatric Hospital	4	11.5	11.06	1 through 31
NR	28	F	MA	Autism, mental retardation, depression, and seizure disorder	grabbing, biting, kicking, head banging, biting self unti bleeding, throwing furniture, tearing hair	Haldol, Celexa	Protestant Guild Learning Center	9	0	0.31	0-2
MR	24	M	MA	Bipolar d/o, pervasive developmental disorders, Oppositional Defiant d/o, Moderate mental retardation	major disruptive, destructive and emotionally/socially interfering behavior, aggression, suicidal threats, banging objects	Trileptal, Seroquel, Depakote, Lithium, Ativan, Prozac	Franciscan Hospital for Children, Kolburne School, Kennedy Hope, Westwood Lodge, Pembroke Hospital	6	0	0	0

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GR	34	M	NY	Moderate mental retardation	Scratch others, headbutt, hit others, kick others, bite others, verbal threats to exhibit aggressive behavior (to include all attempts), spit at others, throw objects at others.	Haldol, Cogentin, Buspar, Ativan, Mellaril	Mount Laredo Center. Devereaux, Ashfrod Home, Bellvue Hospital	24	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
DR	23	M	MA	Autism	physical aggression toward others (hitting, kicking, slapping, biting, throwing objects), self injury (pressurize ears, throw/drop self to floor, leave supervised area), smear saliva, mucus, or any bodily fluids, property destruction, yelling, noncompliance	1:1 staffing, restraint	May Institute, New Boston	26	7	9.22	1 through 27
ER	36	F	MA	Mental Retardation; Autism	disorientation, removing clothes in public, laughing inappropriately, self injury, aggression, incontinence, grossly inappropriate sexual behavior, fecal smearing, banging windows	Dilantin, Mellaril, Luminal, Ritalin, Vistaril, Klonopin, Zyprexa, Neurontin, Trazodone, Ambien, Clozaril	Children's Hospital in New York, Coamo Mental Health Center, Hosta School, Rosario Berber De Arbonito Institute, Bridge Behavioral Program , Developmental Disabilities Program (Fuller Hospital), Jewish Hospital	4	1	1.18	0-4
GR	16	F	NY	Autism, Disruptive behavior disorder NOS	Pull own hair, hurt self or injure self (to include: pinch self, pick scabs, scratch self forcefully), head bang, hit head with hand/knees, bite self.Assaultive behavior (to include hit others, push others, scratch others, pinch others, grab others forcefully, kick others, pull others hair, bite others, head butting, throw objects at others).	Risperdal, Clonidine, and Geodon	had never attended any formal schooling, day or residentia	16	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		

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BS	38	M	NY	mental retardgation, pervasive developmental disorders, Tuberous Sclerosis, Seizure Disorder	self injury (vomiting, ruminating), aggression, property destruction, eating inedible objects, running from supervision	Haldol	Shield Institute	18	16	16	0-43
SS	23	M	NY	Pica, Personality Chang, disinhibited type due to static perinatal encephalopathy associated w/ mental retardation and autism (PDD?). R/O Mood D/O., Autistic D/O	assaultive behavior (hit, kick, scratch, bit, head butt, pinch, pull others' hair), head banging, slamming body against objects, scratching to self to cause redness, touch/rub eye, rub face/chin/neck on shoulder or objects, raise hand above shoulder, slap head, touch hair, pull hair, knee to chin, drop self to floor, noncompliance, inappropriate urination/defecation, property destruction, scream/yell, socially interfering behavior	Risperdal, Prozac, Depakote, Abilify, Seroquel	Developmental Disabilities Institute, AHRC, Anderson School	7	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
YS	30	M	NY	Mild mental retardation, Cerebral Palsy, Psychotic Disorder, Conduct Disorder, R/O Borderline personality disorder, NOS	physical aggression toward others (biting, grabbing, punching, hitting kicking pinching, slapping), verbal threats, possession of potential weapons/sharp objects, smear feces on others, throw objects at others, sexually aggressive statements/threats, spitting at others, aggressive posturing, property destruction, self injury (eating inedible objects, smear self with feces, runaway), major disruptive behavior (swear, yell, scream, steal, expose genitals, disrobing, sexual comments, masturbating at inappropriate times/places, inappropriate sexual touching others, disruptive talking at inappropriate times, pulling fire alarm/dialing 911	Risperdal, Chlorpomazine, Thorazine, Depakote, Zoloft, Vistaril, Topamax, Wellbutrin, Ativan, Paxil, Lithium	Sagamore Children's Psychiatric Center, Tradewinds Education Center (UCP), Pinefield's Children Unit, Mohawk Valley Psychiatric Center,	3	Patient no longer requires aversive therapy with GED device		

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NS	48	M	NJ	Mental Retardation; Autism	Aggression (hit, bite, scratch, and kick others), self injury (screaming, hitting self, giving himself blue/black eye, picking gums until they bleed), bounce in seat or while standing, noncompliance	Mellaril, Thorazine, Stelazine, Benadryl, Dexedrine, Ritalin	Mount Caramel Guild, Forum School	158	Patient no longer requires aversive therapy with GED device		
SS	21	F	NY	Autism	Aggression (biting, lunging at others, biting others' hair, head butting, scatching, pinching, hitting, kicking, grabbing), self injury (head banging, hitting self, running away, scratching self, forceful movement on head into object, pinching self, placing inedible objects in mouth and ears, poking objects into his ears, pulling hair), major disruptive disorders (body slamming, masturbating in public, spitting at others), noncompliance	Physical restraints, Ritalin, Mellaril, Stelazine,	Anderson School,AHRC	2	0	0.94	0-7
MS	49	M	MA	Mental Retardation; Autism	Bite others (to include lunge at others in an attempt to bite), scratch others, pinch others, hit others, kick others, grab others, charge at others.Bite self to cause injury, scratch self to cause injury, pinch self to cause injury.	Ritalin, Mellaril, Steallzine	Telesis Academy, May Insitute, AMIC, Fernald School	80	0	0.22	0-2
HS	48	F	MA	Mental retardation, autism	Physical Aggression toward others, including attempts (e.g. bite others, scratch others).Bite self, objects in ears/eyes, pick fingers, pinch self.	Phenobarb, Dilantin, Restraint, Ritalin Dexdrine and Depokote	Greenshire School, Leslie Cutler Center, May Institute	105	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
HS	18	M	NY	Autism, ADHD NOS, Severe Mental Retardation, Cleft lip and Palate, Craniofacial dysmorphism r/o hearing loss	aggression (kicking and biting, punching, scratching), health dangerous behaviors (hitting and biting self, head banging), inappropriate urination, noncompliance	Restraints, Inderal, Risperdal, Ritalin, Tenex	Huntington Station (New York), Melmar	4	0	0.22	0-4

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Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
JS	39	M	MA	Mental Retardation, Autism	extreme aggression (grabbing, kicking, head butting), inappropriate urination/defecation, scratching self, eating inedibles, screaming and yelling, taking off clothes, manipulating objects, loud repetitive noises	Mellaril	Jersey City School, Shield Institute	22	0.5	0.78	0-3
SS	31	M	VA	Autism, mental retardation, Organic Affective Disturbance	aggression, health dangerous behaviors (hitting self, biting, head banging)	Physical restraints, Ritalin, Mellaril, Haldol, Paxil, Lithium, Naltrexone, Depakote, Valium, Seroquel, Thorazine, Klonopin, Prozac, Benedryl, Ativan, Secretin, Prolixin, Cogentin, Droperidol	Grafton Residential School, Tucker's Pavilion, Virginia Treatment Center, A. Brown Schools Hospital for Children and Adolescents, Kennedy-Krieger Institute, Cumberland Hospital	1	0	0.06	0-1
CS	31	M	NY	Schizophrenia Paranoid Chronic, Depressive Disorder NOS	Aggression, health dangerous, destructive, noncompliant, inappropriate verbal, and educationally interfering behaviors	Risperdal, Zyprexa, Wellbutrin, Haldol, Thorazine, Valium, Neurontin, Abilify, and Tripleptal, Zyprexa, Wellbutrin	Bronx Children's Psychiatric Center, Harlem Hospital Child & Adolescent Program, St. Luke's Hospital Day Treatment Program	16	1	1.39	0-6
BS	47	M	MA	Mental Retardation, Autism	biting, scratching, pulling hair of others', banging and slapping his head, throwing himself to the floor, property destruction, throwing objects, eating inedible objects, rocking, manipulating objects, noises and silly laughing	Mellaril, Thorazine, Cogentin	May Institute, Efficacy Research Institute	87	0	0.56	0-2

** Patients highlighted in green no longer require aversive therapy to control their harmful behaviors*

Utilization of GED Devices for Patients Currently Enrolled at JRC

Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
BS	27	M	VA	Pervasive developmental disorders w/ Autistic features, also includes S/P Cataract surgery, OU, with right-sided glaucoma, S/P right optic ablation, S/P hernia repair and orchioplexy	Aggression, self injury, major disription, noncompliance	Wearing a helmet, communication training, seclusion, physical restraints, one-to-one staffing, Elavil, Haldol, Mellaril, Ritalin, Chorohydrate, Thorazine, Ativan, Periactin, Clonidine, Risperdal, Guanfacine, Nalrexone, Verpamil, Xanax, Inderal, Lithium, Zyprexa.	Virginia Treatment Center, Cumberland Hospital, Au Clair Treatment Center, Grafton Group Home	7	1.5	2.11	0-6
RS	22	f	NY	Autism, Impulse Control s/o, ADHD and PICA	Aggression, health dangerous, destructive, major disruptive, noncompliance (hit head with knees, yell/scream, pull others' hair, pinch self, scratch self forcefully, remove or attempt to remove GED devices, grab others, eat inedibles, head bang, poke eyes)	Depakote, Clonidine, Congentin, Luvox, Risperdal	Bancroft Neurohealth, Margaret Chapman School	3	2	1.83	0-5
MT	50	M	MA	Mental Retardation; Autism	tantrums, screaming, throwing objects, kicking, forceful physical aggression towards others, hitting self, hitting head on hard objects to surfaces, breaking or damaging objects, body rubbing (masturbating, rubbing genitals) in pubic	Serentil, restraint, helmet	New Bedford School for the Retarded, Beverly School for the Deaf, Firecrest School, Amego Education Program, Avalon School	87	Patient no longer requires aversive therapy with GED device		
AT	42	M	NJ	Mental Retardation	spitting, hitting, biting, screaming, using profanity, inappropriate urination	Lithium, Ritalin, Strattera, Risperdal, Geodon, Eskalith, Seroquel, Thorazine	Northside Center for Child Development	75	Patient no longer requires aversive therapy with GED device		
RT	17	M	NY	ADHD, Oppostional Defiant d/o, Attachment d/o, Expressive Language d/o	aggression toward others, throwing objects, breaking furniture, sticking a paperclip in an electrical socket, inappropriate urination	Lithium, Ritalin, Strattera, Risperdal, Geodon, Eskalith, Seroquel, Thorazine	Mount Sinai Hospital, Saint Vincents Hospital	12	Patient no longer requires aversive therapy with GED device		

** Patients highlighted in green no longer require aversive therapy to control their harmful behaviors*

Utilization of GED Devices for Patients Currently Enrolled at JRC

Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
MV	29	M	NY	pervasive developmental disorders, Depressive d/o, Obsessive d/o by Hx, Mild mental retardation	Aggression, obsessive behaviors, nonfunctional body movements, self injury	Zyprexa, Seroquel, Depakote, Clonidine, Paxil, Thorazine PRN	Anderson School, St. Francis Adolescent Psychiatric Unit	6	1	1.33	0-7
EV	49	M	MA	pervasive developmental disorders, Severe mental retardation	ritualistic behaviors, extreme aggression against others, self-injury, property destruction, non-compliance	One-to-one staffing, immediate rewards, restraints, redirection, Haldol, Mellaril, Thorazine, Phenobarbal, Dilantin, Valium, dalmane	Devereaux School, McLean Hospital, Metropolitan State Hospital, Avalon School, Metropolitan State Hospital	81	0	0.17	0-1
BW	22	M	MA	Autism, Severe mental retardation, ADHD, Acquired Brain Injury, and h/o removal of choroids plexus papilloma. Due to previous dx, he has behavioral problems and has been diagnosed as having Impulse Control D/O. (H/O PDD dx and dev. delays at age 2)	Self injury (pinching self, biting self, putting hand through glass pane), pica, running away, stripping, hair pulling (to the point of baldness on his scalp), climbing on and jumping off high furniture and over railings, rectal gouging, smearing feces, cyclic hyperactive behaviors	One-to-one staffing, physical restraint, Remeron, Melatonin, Tenex, Risperdal, Depakote, Adderall, Gabitril, Seroquel, Strattera, Ritalin, Clonidine, Mellaril, Zyprexa, Risperdal, Trileptal, Haldol, Buspar, Thorazine, Xanax (PRN for anxiety)	Bancroft Neurohealth Center, Heartspring,	5	3	4.33	0-14
JW	41	M	NY	Mental Retardation, Autism	Severe aggressive behavior, self injury, property destruction, disrobing, grabbing women's breasts and feet, throw self to floor, head banging, noncompliance	Physical restraints, Thorazine, Haldol, Navane, Corgard, Mellaril, Proxlin, Atarax	Rose Kennedy Center, Teacher-Mom Program (New York), Public School 93 for Autistic Students (new York), Shield Insitute, Anderson School	30	0	0.11	0-1
SW	44	M	NY	Mental Retardation, Autism	Extreme aggression, self injury resulting in hospitalization	Haldol, Ritalin, Paxil, Lithium, Chlorpromazine	Charles Drew Day Care Center, Shield Institute, Samuel Field YM-YOHA	51	0	0.06	0-1

** Patients highlighted in green no longer require aversive therapy to control their harmful behaviors*

Utilization of GED Devices for Patients Currently Enrolled at JRC

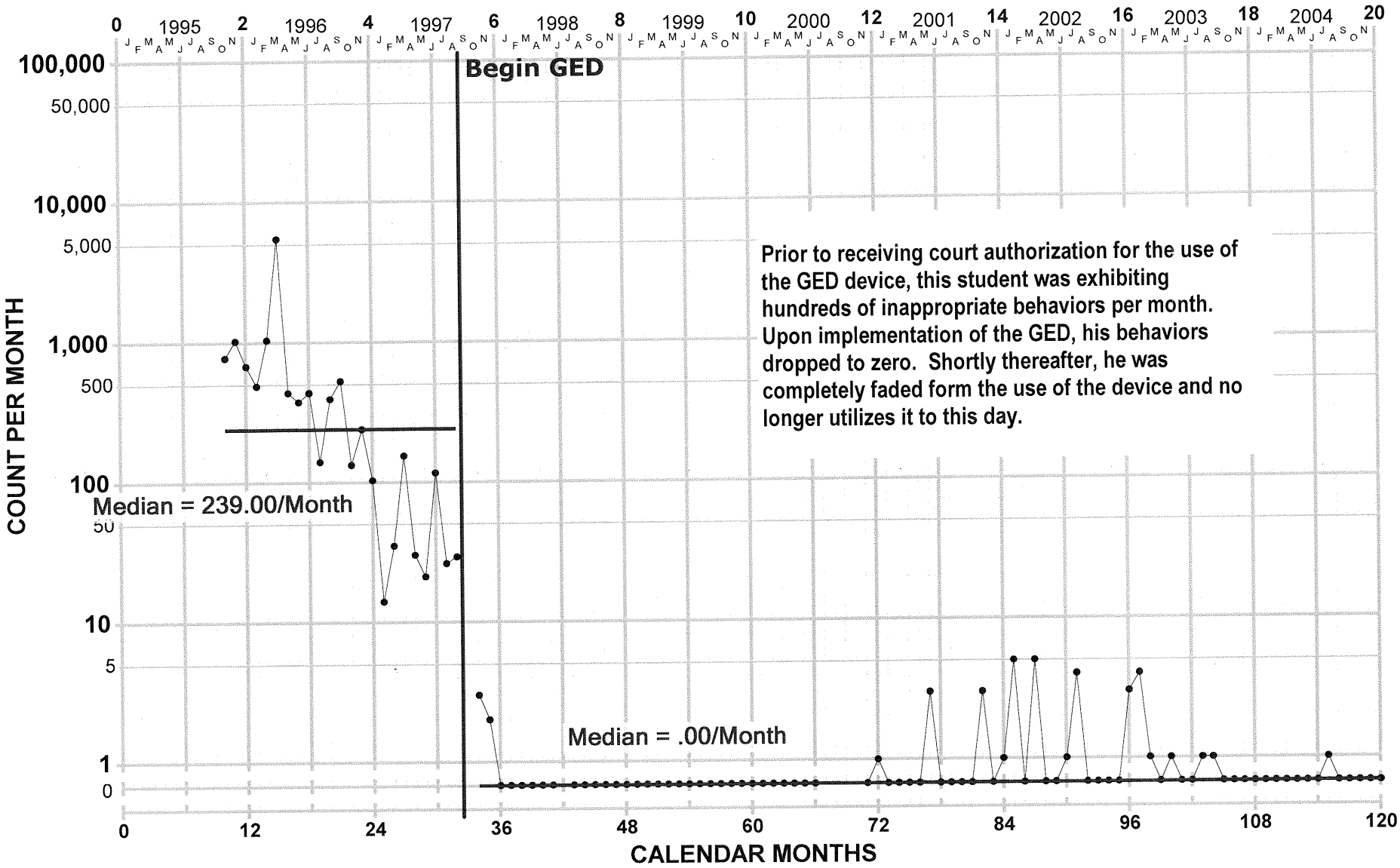
Initials	Age	Sex	State	Diagnoses	Behaviors	Previous treatments	Prior Institutions	# months at JREC prior to GED treatment	Weekly Median (6 months)	Weekly mean (6 months)	Weekly Range (6 months)
JW	19	M	NY	Mental retardation, multiply disabled	Hit others, push others, scratch others, forcefully grab others, kick others, bite others. Bite self, hit self, smear feces on self/others, slap face/legs, clap/slap hands forcefully to cause redness, eat inedibles	arm splints, restraint, Risperdal and Benadryl, 1:1 staffing	Elmhurst Hospital	39	Patient successfully treated with aversive therapy. GED no longer included in treatment plan.		
BW	24	M	NY	Autism	Aggression (hitting, kicking, pinching, biting, head butting), property destruction (clearing tables, thowing large objects, repeatedly flushing toilets until they broke), health dangerous behaviors (yelling, climbing on furniture), noncompliance	Depakote, Zyprexa, Olanzapine and Cogentin, Ricifinal, Ritalin, Mellaril	Shield Institute, Bellevue, Children's Village, Saint Christophers, QCPC	13	0.5	1	0-4
JW	21	M	VA	Autism	extreme aggression, health dangerous behaviors, major disruptive behaviors, tantrums	Pyschotropic medication (Abilify, Risperdal, Depakote, Geodon, Neurontin, Seroquel, Thorazine), behavior modification, one-to-one staffing, physical	Virginia Institute of Autism, Benedictine School, Commonwealth Center for Children	11	0	0.56	0-3
MW	28	F	NY	Severe mental retardation, Mood Disorder NOS, Down Syndrome	self-abuse/health dangerous behaviors, aggression toward others,	Haldol	The Institute for Basic Research, Development Clinic at Bellevue Hospital	4	1	1	0-4

** Patients highlighted in green no longer require aversive therapy to control their harmful behaviors*

Attachment 3

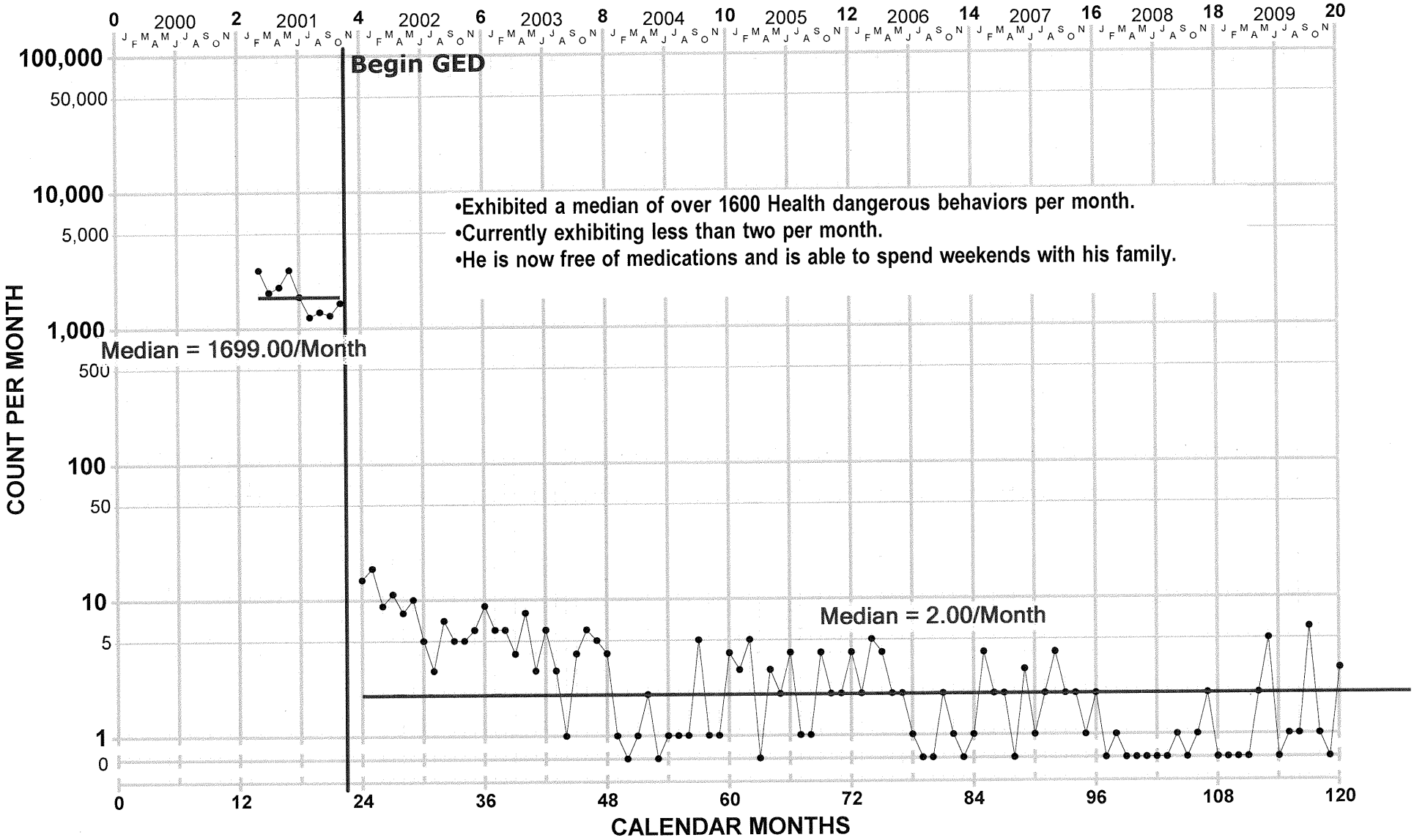
Patient behavior tracking charts

MONTHLY CHART



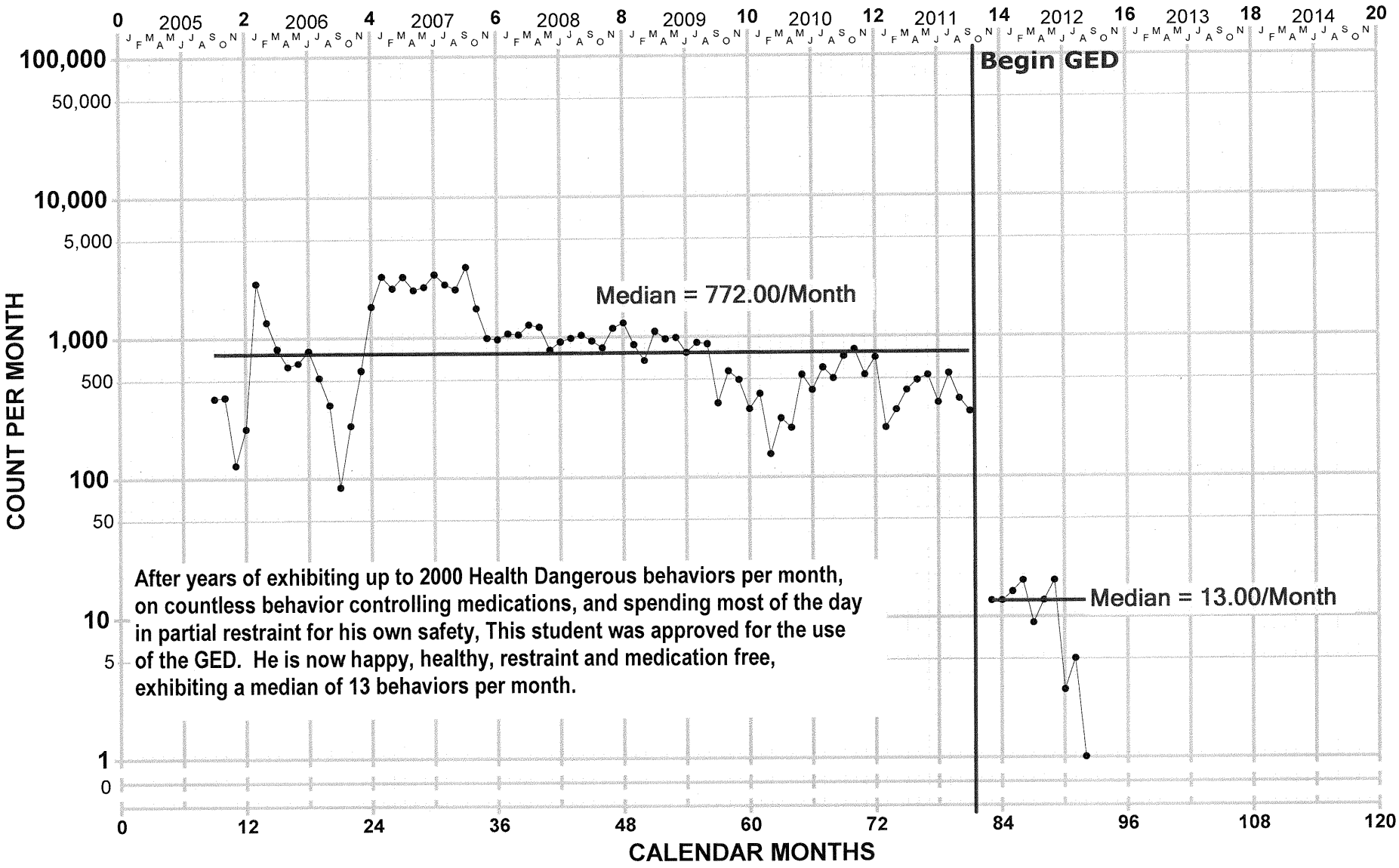
RP	CM		
CASE MANAGER	CLINICIAN		
GR		Health Dangerous 1	*Eat food/drink from floor/trash, leave supervised area, pick fingers, any inappropriate urination or defecation, spit (not at others), scratch self to cause bleeding, intentionally vomit, touch or wipe urine on his body, spit food out and put it back in his mouth again.*
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



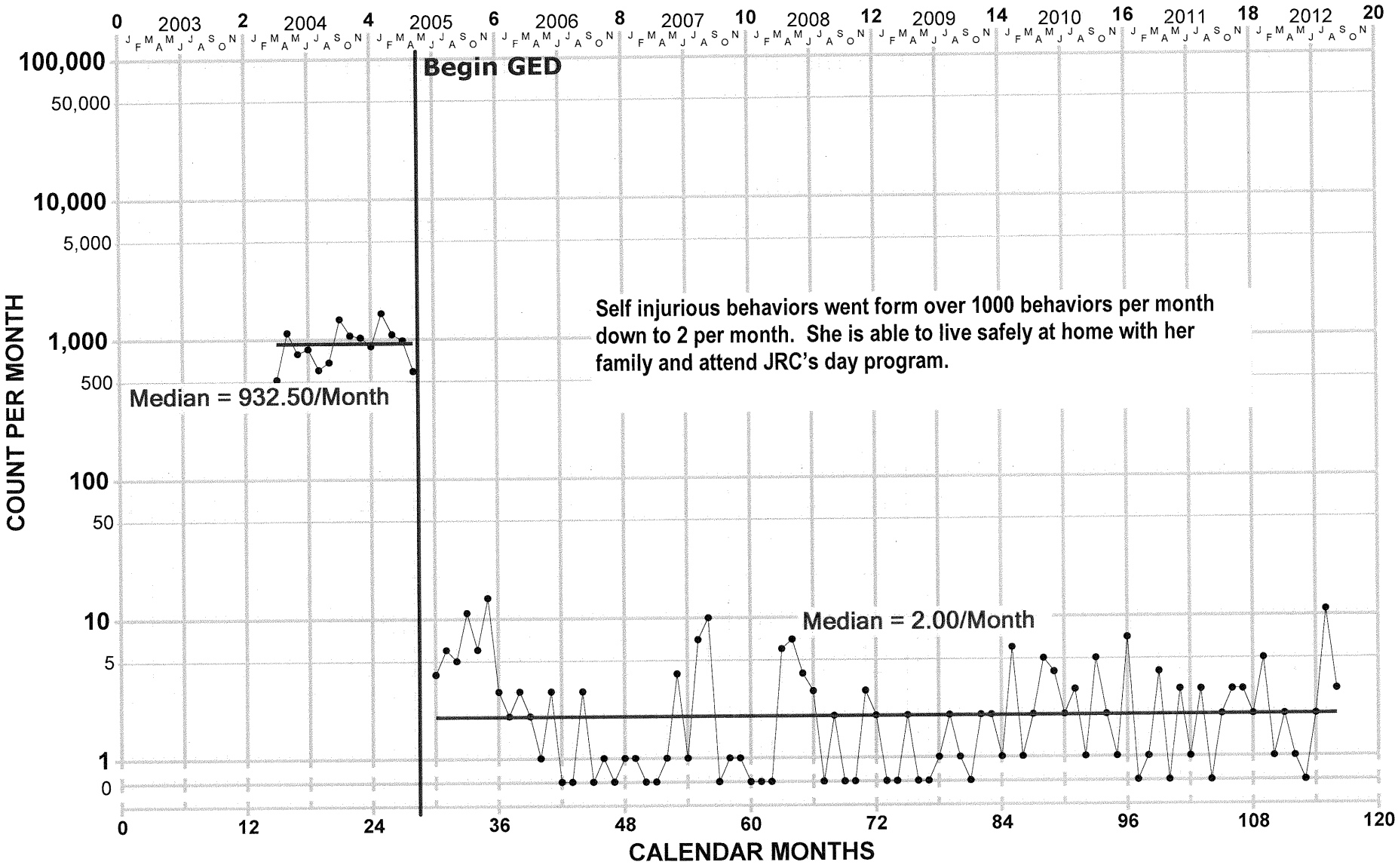
FA	NB		
CASE MANAGER	CLINICIAN		
CL	AB	Health Dangerous 1	*Attempts to hurt/injure self, leave supervised area, runaway (including attempts), place objects and/or finger into electrical sockets, run towards oncoming traffic, touch/remove GED device, stepping off the treadmill while it is in motion.*
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



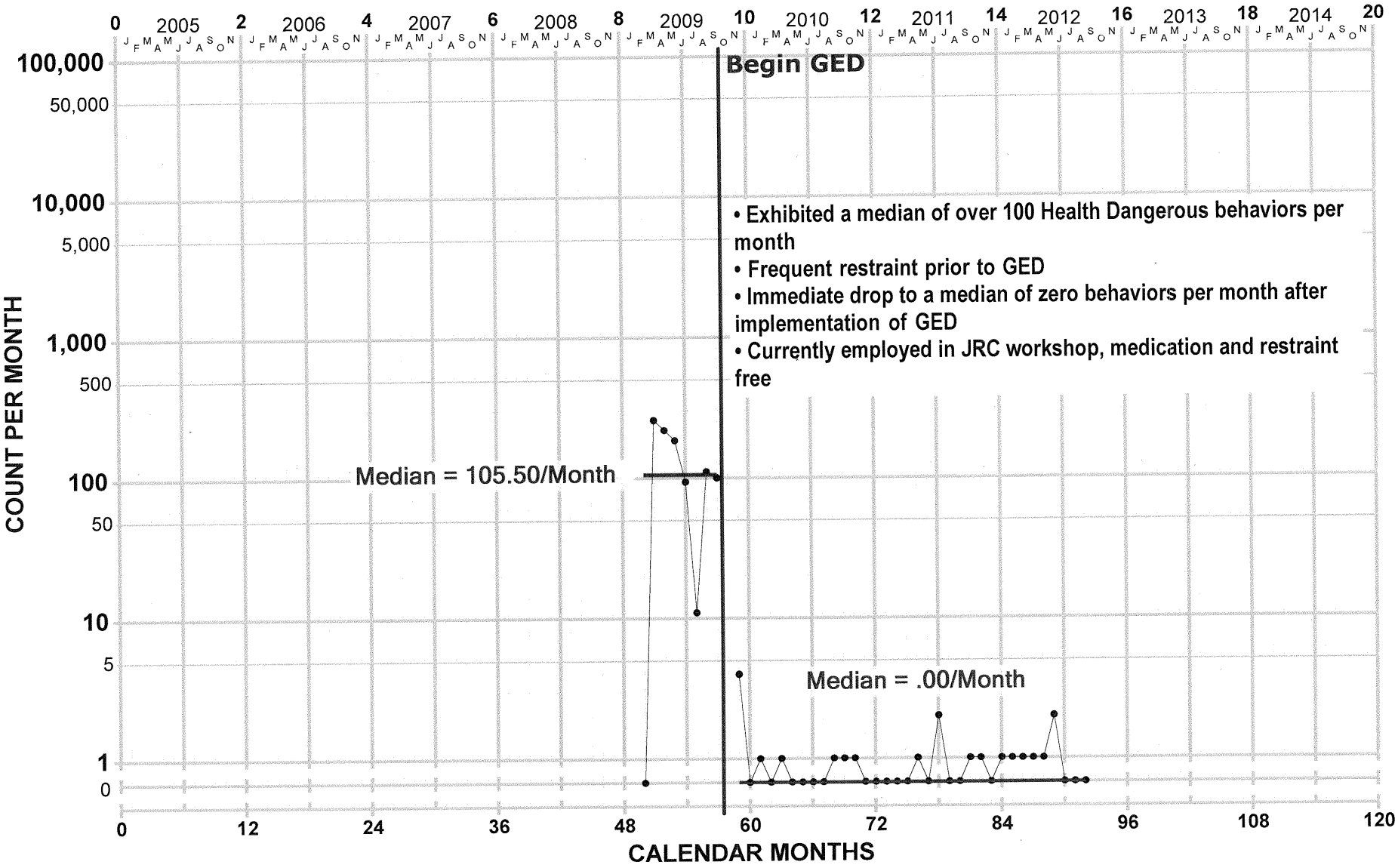
RA	NB		Hurt self (including attempts) bite self, bang head, hit self (e.g. punching, slapping self), scratch self, pinch self, slam body parts together (e.g., slam/bang legs or knees together with force), slam body parts against objects (e.g., hitting wall with hand, hitting chair with knee).
CASE MANAGER	CLINICIAN		
AP	MS	Health Dangerous 1	
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



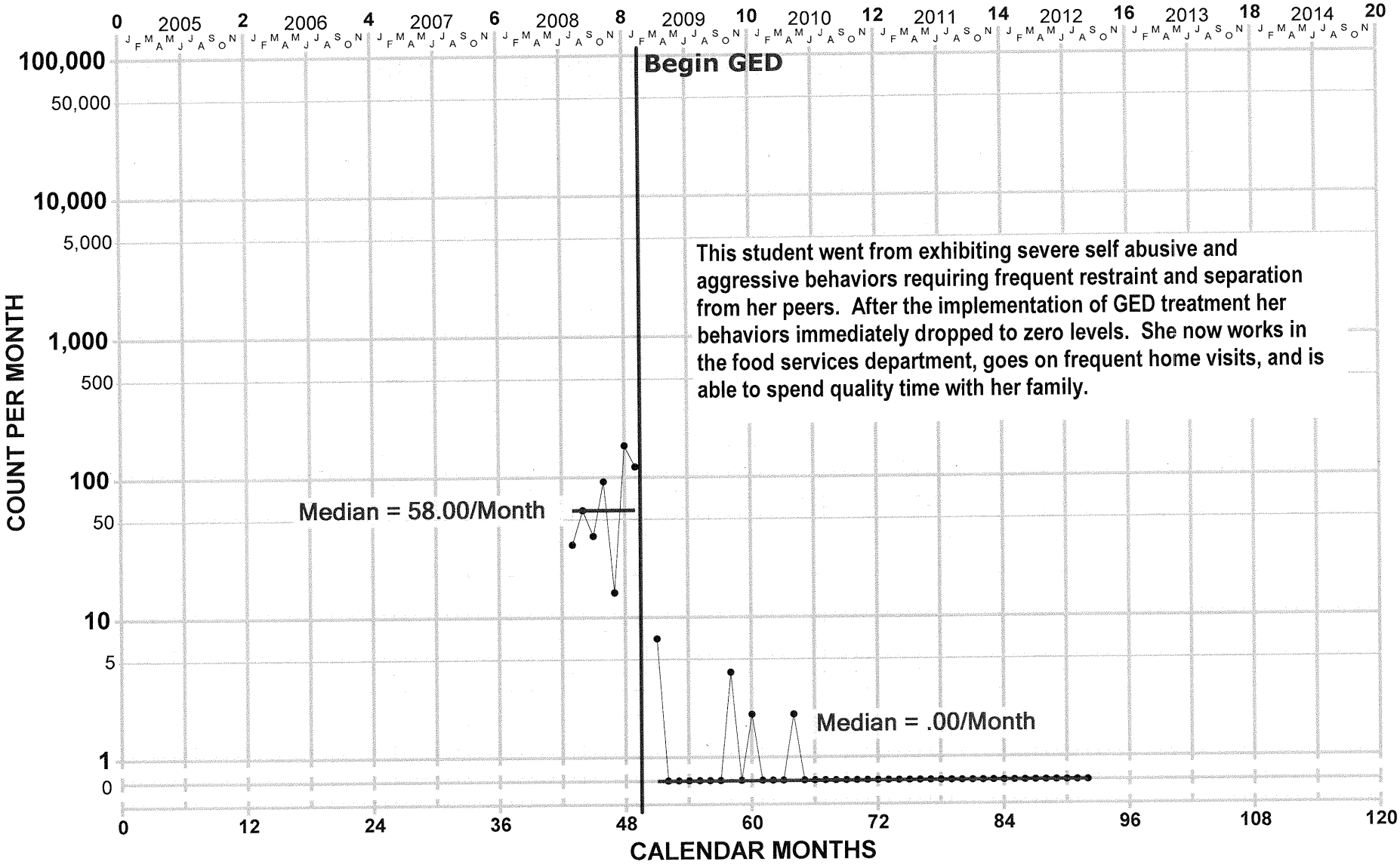
fa	*RvH*		*Attempt to harm self to include attempts (to include hit self or scratch self to cause redness), bang body parts against objects to cause redness (to include bang head on walls or floor), push hand against her face (chin/forehead) to cause bruising.*
CASE MANAGER	CLINICIAN		
NM		*Health Dangerous 1*	
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



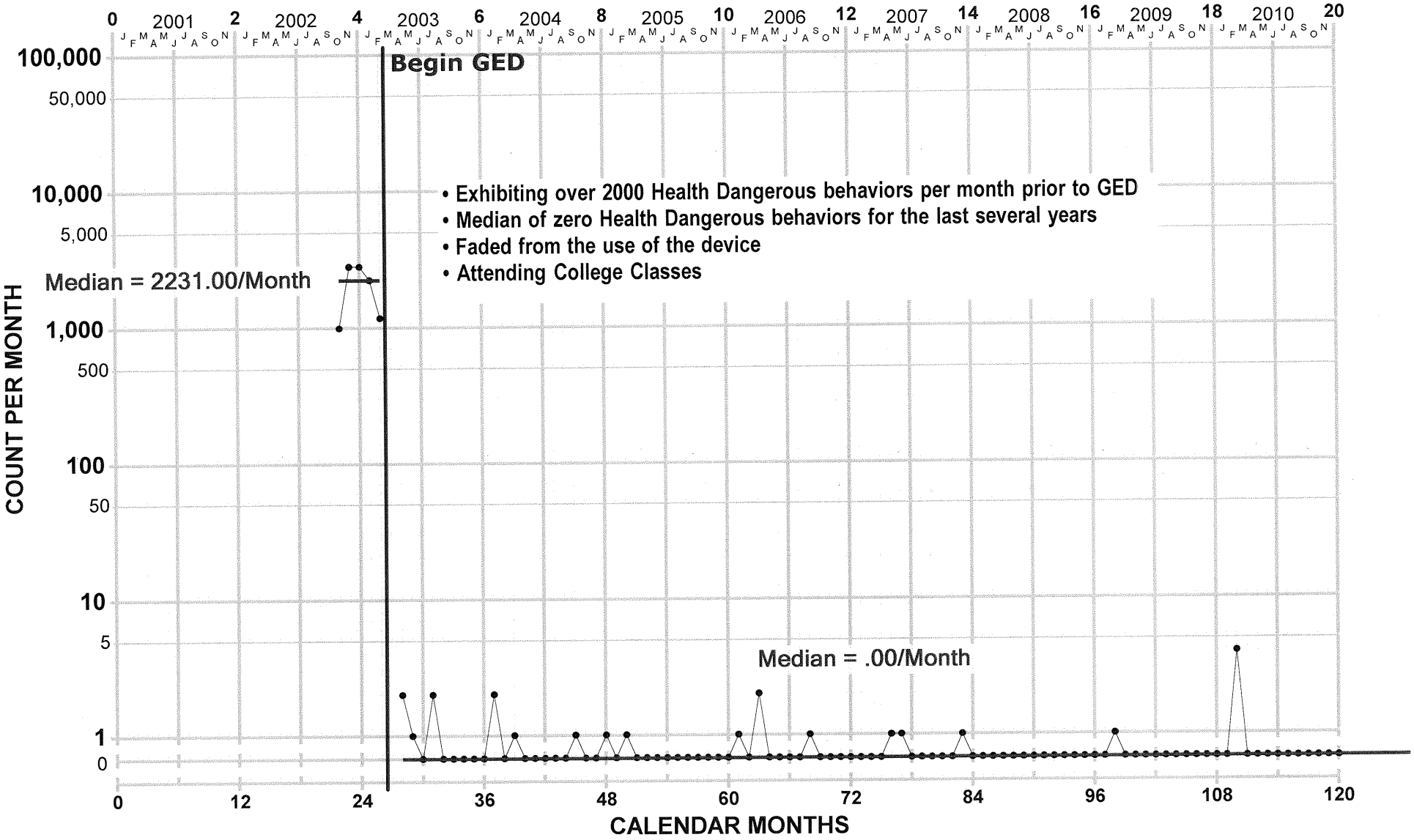
FA	*CG*		
CASE MANAGER	CLINICIAN		
TC		*Health Dangerous 1*	*Bang head, hitting self.*
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



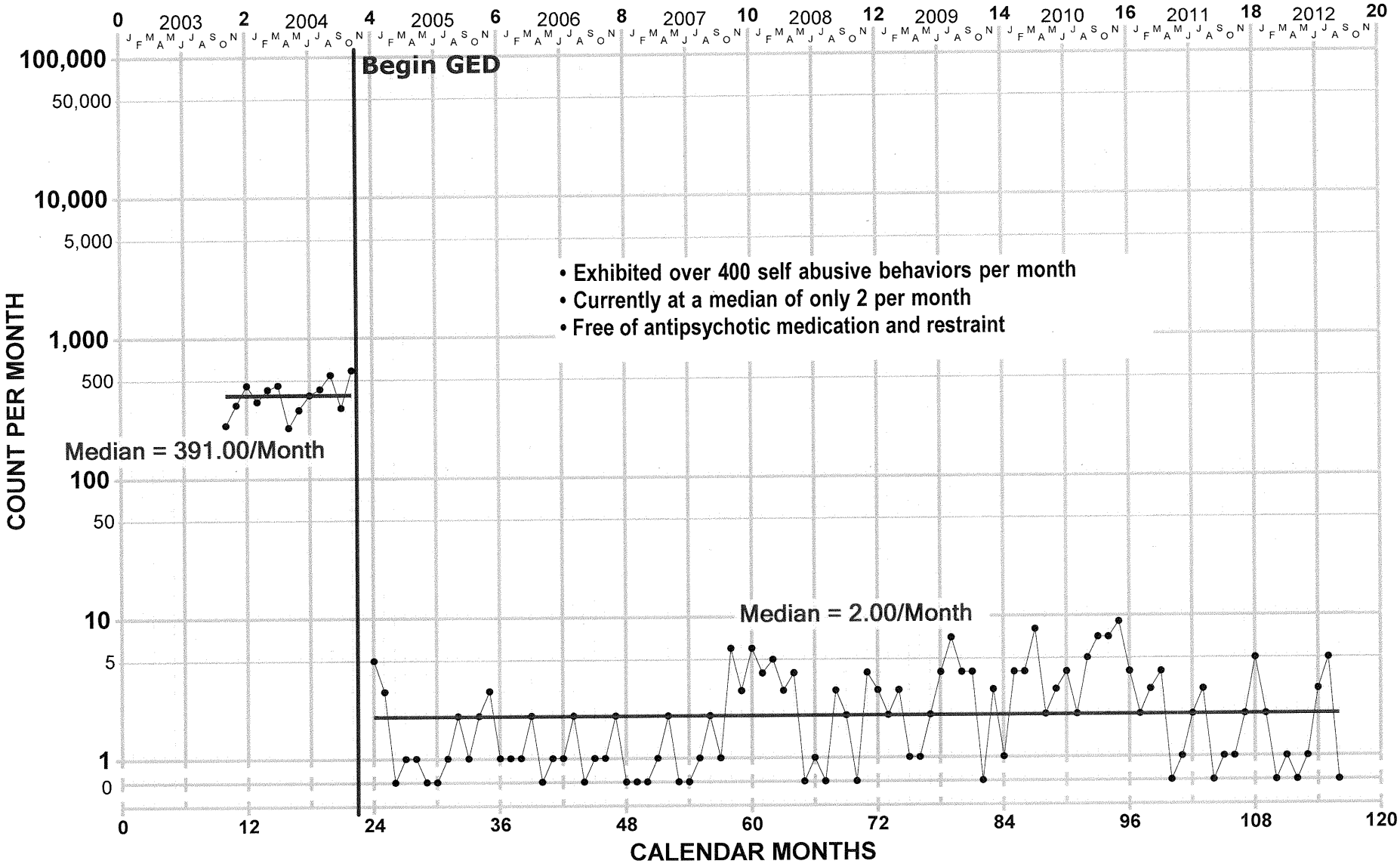
RA	*NB*		
CASE MANAGER	CLINICIAN		
LE	*CG*	*Health Dangerous 1*	*Head bang, run away, induce vomiting.*
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



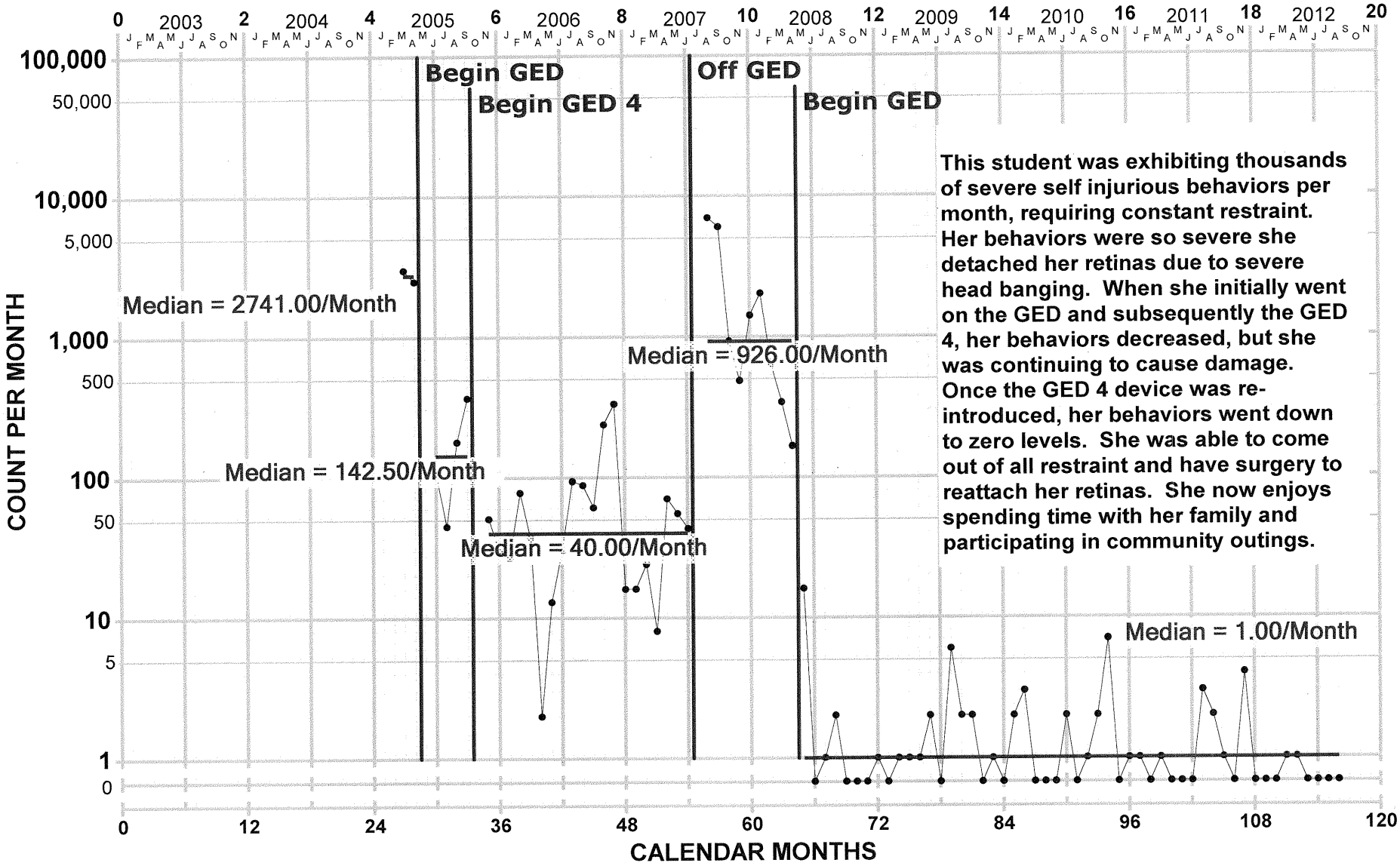
TC	JR		
CASE MANAGER	CLINICIAN		
MP		Health Dangerous 1	Hurt self, pull out body hair, scratch self to cause injury, pick skin to cause bleeding, runaway to include attempts, leave supervised area.
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



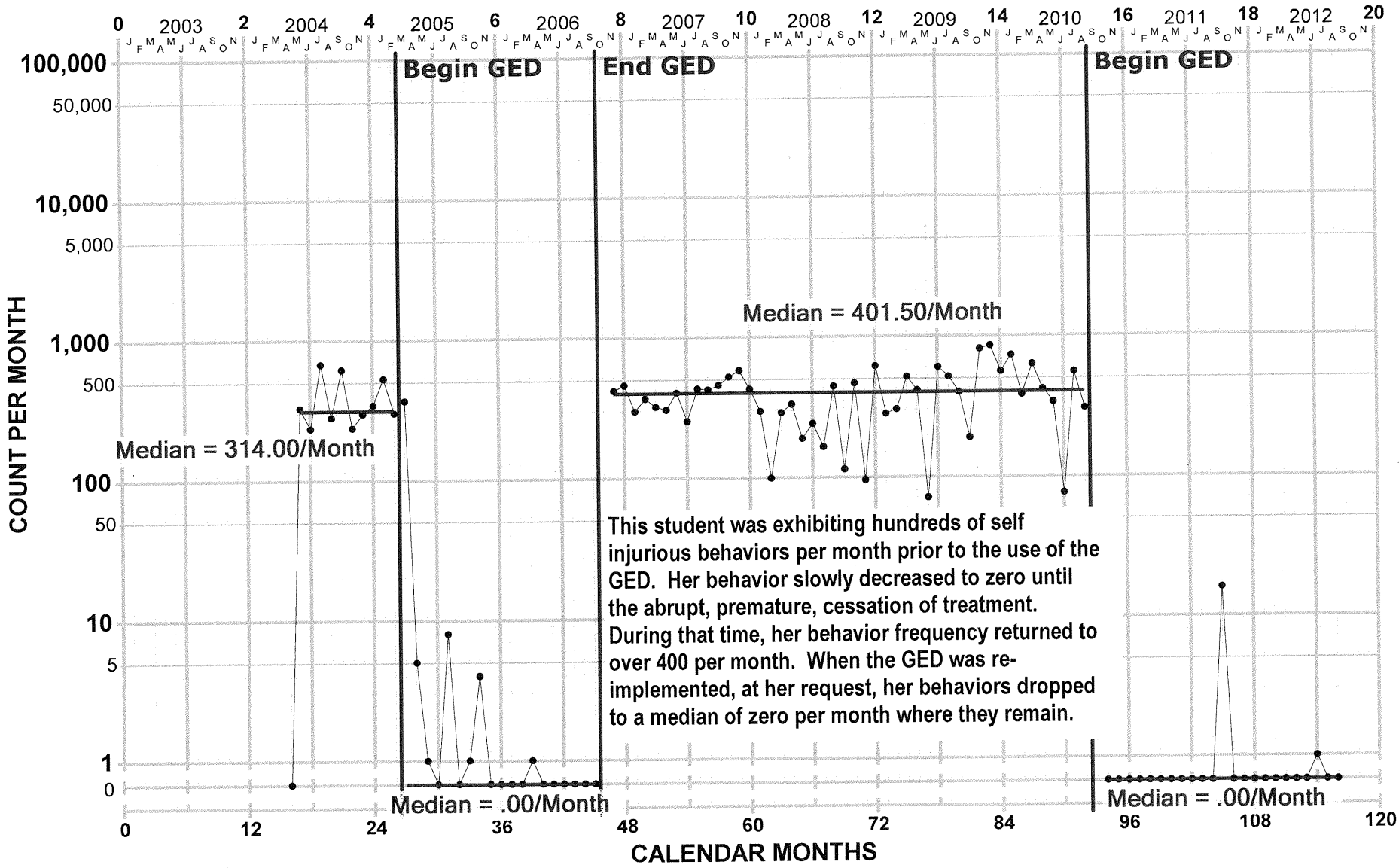
FA	RvH		
CASE MANAGER	CLINICIAN		
BW		Health Dangerous 1	Attempt to harm self such as hit self, scratch self, pinch self, bite self, punch self, pick skin, bang head, leave supervised area, runaway.
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



NE	NB		
CASE MANAGER	CLINICIAN		
SS	MS	Health Dangerous 1	Head bang, slam body against objects, scratch self to cause redness, touch rub/eye (to include on objects), rub face/chin/neck on shoulder or objects, raise hand above shoulder, slap head, touch hair (on head or neck), pull hair, knee to chin to include ALL attempts, drop self to floor (to exclude tripping), remove foot/feet from footboard (during a 10 minute session), remove hand from holster (during a 10 minute session), attempt to remove device.
NAME	TEACHER	ITEM MEASURED	COMPONENTS

MONTHLY CHART



FA	RvH		Harm or injure self (i.e. bite self, hit self, scratch self, bang head), drop self forcefully/throw self to floor, forceful head movements (such as whipping neck forward or backward forcefully), knee self in face, pull hair out.
CASE MANAGER	CLINICIAN		
LJ		Health Dangerous 1	
NAME	TEACHER	ITEM MEASURED	COMPONENTS

Attachment 4

Opinion of Dr. Sassaman regarding the dangers of stopping aversive therapy

Edward A. Sassaman, M.D.
Excellus BlueCross BlueShield
165 Court Street
Rochester, NY 14647

December 18, 2012

Karen Archdeacon
Compliance Officer
Food and Drug Administration
One Montvale Ave, 4th Floor
Stoneham, MA 02180

RE: December 6, 2012 U.S. Food and Drug Administration Warning Letter

Dear Ms. Archdeacon:

I am in receipt of the U.S. Food and Drug Administration's ("FDA") December 6, 2012, Warning Letter to the Judge Rotenberg Educational Center, Inc. ("JRC") and have been asked to provide a medical opinion on the potential consequences of discontinuing the JRC client's behavioral treatment with the Graduated Electronic Decelerator ("GED") 3A and 4 skin shock devices ("GED devices") before it is deemed clinically appropriate to do so.

I have been a consulting physician to JRC for over thirty years. In this capacity, I follow the health and progress of all of JRC's clients. I visit the JRC facility and examine its clients on a monthly basis. In addition, I speak with the nursing staff at JRC on a daily basis, often having multiple conversations with them daily, to consult on client and medical issues. I also conduct a yearly physical and medical records review for each JRC client.

A brief summary of my credentials is as follows. I graduated from Harvard Medical School in 1973 and completed my residency and fellowship at Children's Hospital Medical Center in Boston, Massachusetts. My fellowship was in Developmental Disabilities. I am a registered Board Certified physician, licensed to practice in Massachusetts since 1976 and in New York since 1994. I am Certified by the American Board of Pediatrics in the area of General Pediatrics and am a Fellow of the American Academy of Pediatrics. Currently, and for approximately the past six years, I have served as an Expert Reviewer in Pediatrics for the Office of Professional Medical Conduct in Albany, New York, as appointed by the New York Department of Health. I serve as the Regional Medical Director of Excellus BlueCross BlueShield, Rochester Region, in Rochester, New York, where I am responsible for developing and implementing managed care programs for children throughout all of the Excellus network. Attached at Tab A is my curriculum vita.

I am familiar with the behavior modification treatment given by JRC to its clients, including the operation and effect of the GED devices. Since 1990, I have been following the health of all of the hundreds of JRC clients that have received treatment with the GED devices at

JRC. One of my duties at JRC is to examine the JRC clients before they receive skin shock treatment with the GED devices and determine whether there are any medical contraindications to using the GED devices with that particular client. I have examined hundreds of clients, dating back some twenty years, who were receiving applications of the GED devices. These clients suffer from severe behavior disorders that have caused them to inflict severe physical harm on themselves as well as others.

Per my review of the December 6 Warning Letter, it is my understanding that JRC plans to seek FDA clearance of the newest version of the GED devices. It is my further understanding that FDA is requesting that JRC provide a transition plan intended to remove each client currently using the GED from this important treatment. I am writing this letter to the FDA to make your agency aware that the GED devices in use at JRC continue to be operating safely and are the only treatment that has been effective with the JRC clients to stop their self-mutilation and other harmful behaviors. Any interruption in treatment with the GED devices, while the new devices undergo FDA clearance, would expose the JRC clients to catastrophic physical harm, including permanent injury and death.

Through my education and training and numerous years of experience treating children who suffer from severe behavior disorders, it is clear that there exists a small population of children who suffer from severe behavior disorders that cause them to attack others and engage in life-threatening self-abuse. These clients have: banged their head to the point of brain damage; bit off their own fingertips; pulled out their teeth; vomited and refused food to the point of starvation; bitten a hole through their cheek; bitten off part of their own tongue; scratched their heel to the point of blood, bone infection and eventual death; broken their own arm; cut off their own earlobe with a scissor; run into moving traffic; punched their eyes causing detached retinas and blindness; pulled out their hair to the point of baldness; swallowed razor blades; and cut their skin with a knife so often that the skin became too tough to be sutured. In addition, many of these clients could not cooperate with necessary medical treatment because their behaviors would prevent medical attention, thereby further threatening their own lives. The JRC clients have received the other available forms of treatment, including drug therapies, in many other programs and facilities, including psychiatric hospitals, prior to placement at JRC and their life-threatening behaviors could not be effectively treated.

JRC has been able to effectively treat these clients' dangerous behaviors with the GED devices and these clients are now all in good health and receiving much needed education, rehabilitation and other essential services. JRC takes all necessary medical precautions in implementing GED treatment. A physician will conduct an initial examination of each client for whom the use of GED treatment is proposed. After the physical examination of the client and a review of his/her treatment records, the physician will make a determination as to whether GED treatment would be contraindicated for that particular client. For those clients that have heart disease or neurological problems, the clients are also cleared by a cardiologist and/or neurologist. JRC will not implement GED treatment if it has been contraindicated by an examining physician.

I have examined hundreds of clients after GED treatment and have never seen any short or long-term negative consequences of any clinical significance. I have never seen any physical harm resulting from the use of GED treatment, other than, in some cases, a very minor reddening

and/or appearance of a scab on the skin site associated with the GED devices. In these cases, however, the minor skin issues were temporary, healed quickly and did not result in any permanent or sustained effects. When applied as part of a structured and consistent behavioral treatment plan, GED treatment poses no medical risks to the clients. Rather, JRC clients who are treated with the GED devices receive tremendous benefits from the treatment. In fact, JRC clients have told me that they needed GED treatment to eliminate their dangerous behaviors and they expressed appreciation for the availability of GED treatment and credited it for saving them from a life of pain and mind-numbing drugs. GED treatment provided them a bright future by allowing them to be educated and to safely access the community and their loved ones.

A discontinuation of this treatment would leave this population without any effective treatment options. These clients would suffer severe physical harm, with their most severe behavior returning and putting these clients at risk of injury include blinding, permanently maiming or killing themselves. They would lose their only opportunity to receive and education and other essential services.

Here is some information on just one of the many JRC clients who would be severely harmed by any precipitous discontinuation of GED treatment. This JRC client, diagnosed with severe mental retardation and pervasive developmental disorder, had a long history of engaging in aggressive and self-injurious behavior prior to his admission to JRC including: hitting and biting family members and caregivers; punching holes in walls; picking at his skin until it bled and then picking at the scabs with such frequency that it took extended periods for the wounds to heal; hitting himself; biting himself and head banging. He would often refuse medical treatment for the injuries he caused himself. Prior to admission to JRC he was placed at several different special education programs, he was frequently hospitalized, and he was prescribed numerous harmful psychotropic medications. These treatments were not successful and the client continued to engage in very dangerous self-abuse and aggressive behavior. In addition, he was morbidly obese, weighing as much as 315 lbs., which was a side effect of the large dosages of psychotropic medication. He was then admitted to JRC where he received positive programming supplemented with GED treatment. This treatment program resulted in the client: engaging in significantly less dangerous behaviors and no longer requiring restraint; making more behavioral progress than he had at any other program; and enabling him to be educated. In addition, he was healthier medically, having lost a significant amount of weight at JRC. Due to funding issues, he was later transferred from JRC and his GED treatment was discontinued. After just three months from his discharge, he experienced such behavioral regression at the new facility they were forced to medicate him, isolate him in a bedroom, and strap him to his bed with posey straps. During the three months, his health deteriorated and he engaged in severe self injury, including picking at and biting his legs, leaving bruises, scratches, scabs and sores all over his body. Because the facility was unable to handle his dangerous behaviors, the facility recommended to the State funding agency that the client be returned to JRC where he can receive GED treatment and the funding agency agreed. This clients remains at JRC today, where: he is receiving GED treatment, which has once again led to a significant reduction in his dangerous behaviors; he is free of restraint; he is healthy and happy; and he is progressing vocationally and socially.

Based on my examinations of all JRC clients receiving GED treatment and my knowledge of their medical history, it is my professional opinion that the GED devices are safe,

have not risked injury to any JRC clients and must continue in order to avoid immediate and substantial risk of permanent injury or death.

Sincerely,

Edward A. Sassaman

Enclosure

CURRICULUM VITAE

Edward A. Sassaman, M.D.
Excellus BlueCross BlueShield, Rochester Region
165 Court Street
Rochester, NY 14647
585-238-3653
ed.sassaman@excellus.com

EDUCATION

Undergraduate:	University of Pennsylvania Biology, BA 1969 – Cum Laude
Medical School:	Harvard Medical School – M.D. 1973

POSTGRADUATE TRAINING

Resident:	Children's Hospital Medical Center, Boston, MA Intern: 1973-1974 Junior Resident: 1974-1975 Senior Resident: 1975-1976
Fellowship:	Children's Hospital Medical Center, Boston, MA Development Evaluation Clinic Fellow in Development Disabilities: 1976-1978

BOARD CERTIFICATION AND PROFESSIONAL LICENSES

Diplomate, America Board of Pediatrics – 1978
Massachusetts – 1976 – Present
Rhode Island – 1978 – 1996
New York – 1994 - Present

PROFESSIONAL EXPERIENCE

2000 – Present

Excellus BlueCross BlueShield, Rochester Region
Rochester, NY
(A national indemnity and managed care health insurance company with revenues of over $4 Billion and 2.2 million covered lives.)
Regional Medical Director

Responsibilities: Responsible for developing and implementing managed care programs for children and adults throughout all of Excellus. Consultant for case management, utilization management, and corporate medical policy for all members.

Direct responsibility for overseeing all of provider credentialing and re-credentialing throughout all of Excellus and Univera. Reports to the Vice President of Medical Affairs and Chief Medical Officer of Excellus BlueCross BlueShield, Rochester Region.

Accomplishments:

- Implementation of community-wide Pediatric Preventive Health Guidelines
- Creation and implementation of disease state management program for Attention Deficit Disorder
- Common credentialing and re-credentialing policies (with specific guidelines for outliers created for all of Excellus and Univera)
- Established linkage between quality and credentialing (system to identify quality outliers and monitor QIP through credentialing)

1994 – 2000

Medical Director, Lifetime Health
Associate Corporate Medical Director, BlueCross BlueShield
Rochester, NY
(A mixed model HMO with 65,000 members and revenues of $82 million)

Responsibilities: Direct supervision of entire medical staff, including affiliated health professionals (125 FTEs). Direct responsibility for utilization management, quality management, case management, pharmacy benefit management, disease state management. Reported to the Vice President of Medical Affairs, BCBS Rochester.

Accomplishments:

- Oversaw doubling in size of medical staff
- Created and implemented disease state management programs in diabetes and congestive heart failure
- Created and implemented physician incentive program
- Created and implemented department and individual PCP quality and utilization yearly goals with method to revise goals based on department and individual performance
- Created peer review process to identify medical errors and create quality improvement process to rectify errors

1990 – 1994

Director of Pediatrics, Kaiser Permanente
Springfield, Massachusetts

Responsibilities: Direct supervision of pediatric staff responsible for quality issues. Practicing pediatrician. Reported to the Director of Pediatrics for Kaiser Permanente of Massachusetts.

Accomplishments:

- Oversaw doubling of pediatric department
- Implemented program for evaluation of handicapped children

1984 – 1990

Practicing Pediatrician
Medical West
Springfield, Massachusetts

Responsibilities: Providing primary care to 2,500 children

Accomplishments:

- Creation of consultative service for developmentally disabled children for a group of 12 practicing pediatricians

1978 – 1984

Associate Director, Child Development Center
Providence, Rhode Island
(A Federally and State-funded multi-disciplinary clinic for handicapped children)

Responsibilities: Direct supervision of pediatric staff and fellows as well as pediatric residents and medical students at Brown University Program in Medicine. Director of Muscular Dystrophy Clinic and Spina Bifida Clinic. Reported to Director, Child Development Center.

Accomplishments:

- Oversaw increase in teaching responsibilities with residents and medical students
- Created outreach program for community-based pediatricians

ACADEMIC/HOSPITAL APPOINTMENTS

1. Clinical Instructor in Pediatrics
   1994 - Present

   University of Rochester School of Medicine
   Rochester, NY
   Associate Attending Physician
   Strong Memorial Hospital
   Rochester, NY

2. Attending Physician 1984 - 1994
   Baystate Medical Center
   Springfield, MA

3. Assistant Professor in Pediatrics 1978 – 1984
   Brown University School of Medicine

Providence, RI
Associate Physician
Rhode Island Hospital
Providence, RI

4. Instructor in Pediatrics 1977 - 1978
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2. Lifetime Health Peer Review Committee – 1995 – 2000

3. Lifetime Health Pharmacy and Therapeutics Committee – 1994- 2000

4. Lifetime Health Medical Management Steering Committee – 1997 – 2000

5. BlueCross BlueShield of Rochester Managed Care Quality Committee – 1995 – present

6. BlueCross BlueShield of Rochester Managed Care Credentialing Committee – 1996 – present

7. Blue Cross/Association for Retarded Citizens/United Cerebral Palsy Task Force to create community based primary care program for developmentally disabled adults – 1998 – present

8. Preferred Care Peer Review Committee – 1998 – present

9. Preferred Care Clinical Quality Team – 1998 – 2000

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Attachment 5

Copies of supporting literature

- Duker, PC, Seys, DM. A quasi-experimental study on the effect of electrical aversion treatment on imposed mechanical restraint for severe self-injurious behavior. *Research in Developmental Disabilities*, 2000,p. 235-242.

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ELSEVIER

Research in Developmental Disabilities
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Research in Developmental Disabilities

A quasi-experimental study on the effect of electrical aversion treatment on imposed mechanical restraint for severe self-injurious behavior

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Abstract

Eight individuals with mental retardation and imposed mechanical restraints due to severe, life-threatening self-injurious behavior received electrical aversive treatment. Eight other individuals, who had been matched with the treatment group in terms of the degree of imposed mechanical restraint due to the above problem behavior, had not received electrical aversion treatment. A comparison of imposed mechanical restraint scores, as a measure of severity of self-injurious behavior, between both groups over a period of three years, revealed that electrical aversion treatment significantly reduces the degree of imposed mechanical restraint. © 2000 Elsevier Science Ltd. All rights reserved.

1. Introduction

It is estimated that 5 to 17% of the individuals with mental retardation manifest some form of self-injurious behavior (SIB). Many of them present health-threatening forms of SIB, such as banging their head on objects, eye poking, face scratching, kicking their knee against their face, etc.

During almost three decades, a plethora of interventions to decrease SIB has been used and evaluated (for a meta-analysis, see Didden, Duker & Korzilius, 1997). Nonetheless, SIB often proves to be refractory, requiring us to impose various kinds of mechanical restraint on these individuals to prevent them from

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inflicting life-threatening injuries to their body. Mechanical restraints, including self-restraints, are, however, not in the best interest of the individual in that immobilization leads to detrimental effects on the morphology and physiology of the limbs, not to mention its negative psychological and social effects.

If other, less intrusive treatments have failed, a procedure involving aversive conditioning might be seriously considered. Although various types of stimuli might be employed for this purpose, electrical stimuli have the advantage of allowing the therapist precise administration of the stimuli and strictly control its aversive properties. Electrical aversion treatment (EAT) is applied within the punishment paradigm, concurrently with reinforcing one's behaviors that are functionally and topographically incompatible with SIB or other problem behaviors.

Since the 1960s, EAT has been used in the service system at a small scale for severe SIB and other life-threatening behaviors, such as severe vomiting (Worsham, Israel, von Heyn & Connolly, 1992) and aggressive behavior. A firm conclusion regarding its effectiveness is, however, hard to give as the majority of these studies are based on the $n = 1$ methodology, often with limited long-term data. Even if a group of individuals is treated (see Duker & Seys, 1996), a control group is not employed. Given this situation, there is a strong need to conduct studies that enable us to draw more valid conclusions on the effectiveness of EAT.

The purpose of the present study was to address this issue by reporting on a study with eight individuals who received EAT for severe SIB and who had been matched with eight individuals with severe SIB, who had not received EAT. The study was part of a comprehensive study by the authors in which a group of 104 individuals with various degrees of SIB and imposed mechanical restraints was monitored over several years. The effectiveness of various types of interventions was evaluated. Each individual's degree of mechanical restraint imposed by caregivers was assessed using the Imposed Mechanical Restraint Inventory (IMRI) (Duker & Seys, 1997), three years preceding the second assessment.

2. Materials and methods

2.1. Participants and setting

Eight individuals with mental retardation and severe SIB were enrolled in a clinical program using EAT (see Procedure). There were five males and three females with ages ranging from 18 to 44 in the EAT-group. Each of them lived at a different facility or day-care center throughout The Netherlands. Consent for recording and treatment was obtained from the parent(s) or other family members, all primary caregivers involved, and from a committee of human rights. Eight other individuals, who were matched with the treatment group in terms of the degree of mechanical restraint imposed on them (see Recording) had not received EAT. In the latter group there were three males and five females with

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ages ranging from 15 to 48 years. Consent for recording their degree of imposed mechanical restraint was obtained.

Functional analysis for each of the individuals involved either was impossible to conduct due to the high frequency and intensity of their SIB or analysis had revealed an undifferentiated pattern of variables controlling their SIB. All participants of this study had been exposed to a wide range of treatments, such as psychotropic agents (i.e., neuroleptics, antidepressants), functional communication training, systematic and unsystematic restraint fading, differential reinforcement of other behaviors, and gentle teaching, without any effect on SIB.

2.2. Recording

Data were collected using the IMRI at two points of time, that is, Spring, 1995 ($t1$) and Spring, 1998 ($t2$). The IMRI has shown acceptable levels of interobserver reliability, intraobserver reliability, and accuracy (Duker & Seys, 1997). With this inventory the participants' degree of imposed mechanical restraint was assessed for three positions, that is, 1) being ambulant; 2) sitting in a (wheel)chair (not due to physical handicap); or 3) lying in bed (not due to physical handicap). For each body part involved, increasing degrees of imposed mechanical restraint were defined, ranging from 3 for the neck to 10 for the arms/hands. As a second parameter, duration of imposed mechanical restraint was assessed, that is, number of hours per day with a maximum of 16 h. Recording was conducted by two raters (not the authors), who remained naive to the purpose of this part of the study and were naive as to who was belonging to either the EAT group or the no-EAT group. At $t1$, using the IMRI score (see below) as dependent measure, the Wilcoxon matched-pairs signed-ranks test failed to reveal a statistically significant difference between the two groups, ($z = .76$; $p = .45$).

For each participant a restraint score was calculated by multiplying the degree of restraint, expressed in a percentage, by the number of hours per day the restraint was into effect and dividing this number by the product of the maximum degree of restraint for each of the body parts and maximum duration, times one hundred (see Duker & Seys, 1997). A mechanical restraint score for each participant was then obtained by adding the ambulation score to the sum of the chair and bed restraint scores.

2.3. Reliability

Reliability was defined as the percentage agreement between pairs of raters on the occurrence (i.e., degree and duration) of restraint, thereby including agreement on non-occurrence(s) of restraint within the position involved (i.e., total reliability). To prevent inflation of reliability scores, positions that were not involved were excluded from calculation. Reliability on duration of restraint (irrespective of the degree of restraint) was determined permitting a difference between pairs of raters of two hours or less.

Assessment at $t1$ yielded a mean percentage of 91 for total reliability and a

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mean percentage of 78 for duration. At *t*2, these mean scores were 95 and 85, respectively.

2.4. Procedure

2.4.1. Apparatus

Electrical stimuli (40 mA; 30 Hz; a.c.; impedance range: 1–7 kOhm) were administered remotely using the HSP 3012 (Schoutissen Electronics, The Netherlands). The parts of the device are: 1) a remote control unit with a battery, which, when the button is pressed, transmits a coded signal to the receiver; 2) a receiver (8 cm × 8 cm × 5 cm; 425 g) consisting of an inductorium, a radio frequency receiver, and a 5.5. V battery, held in a belt-bag around individual's waist; administration of the stimulus occurs through two circular electrodes (surface size 1 cm^2, set 40 mm apart) attached to the individual's upper leg or upper arm; and, 3) a charger. The apparatus has been approved by the Dutch, Belgian, and Canadian health authorities.

2.4.2. Treatment

There were three phases in effect for the participants of the treatment group. As a first phase, therapists (i.e., the authors) provided parents, staff, and caregivers with information on the rationale of the treatment, showed them videotapes on therapists' previous treatments with EAT, and had all the people involved experience the electrical stimulus. If consent had been given (which occurred with all individuals for whom this was requested), the therapist completely or partially removed participant's physical restraint(s) and administered response contingent electrical stimuli for each occurrence of the target response during one session (i.e., 30–45 min) to assess the individual's response to the stimuli. If initial suppression of SIB failed to occur, a second session was scheduled. During the session(s), the therapist provided relaxation if a panic response or anxiety by the participant would be manifested. Multiple topographies of SIB (e.g., eye poking and head banging) were not treated simultaneously, but successively.

As a second phase, given sufficient suppression of SIB, the above resulted in introducing the procedure to a case manager, who had a masters degree in psychology and experience in using EAT. This person was in charge of using the procedure in participant's natural environment (i.e., living group, classroom, home) during a large part or the whole day for a period up to several months. The procedure encompassed the following: 1) administration of aversive stimuli, according to the guidelines given by Duker (1998); 2) training and reinforcement of other and incompatible behaviors (e.g., communicative skills); and 3) supervision and feedback to parents and other caregivers on the use of the above components.

The final phase consisted of monitoring by the two therapists (i.e., the authors) throughout treatment. Monitoring could vary from phone calls by the therapist to repeated on-the-spot recording of the administration of the treatment and assess-

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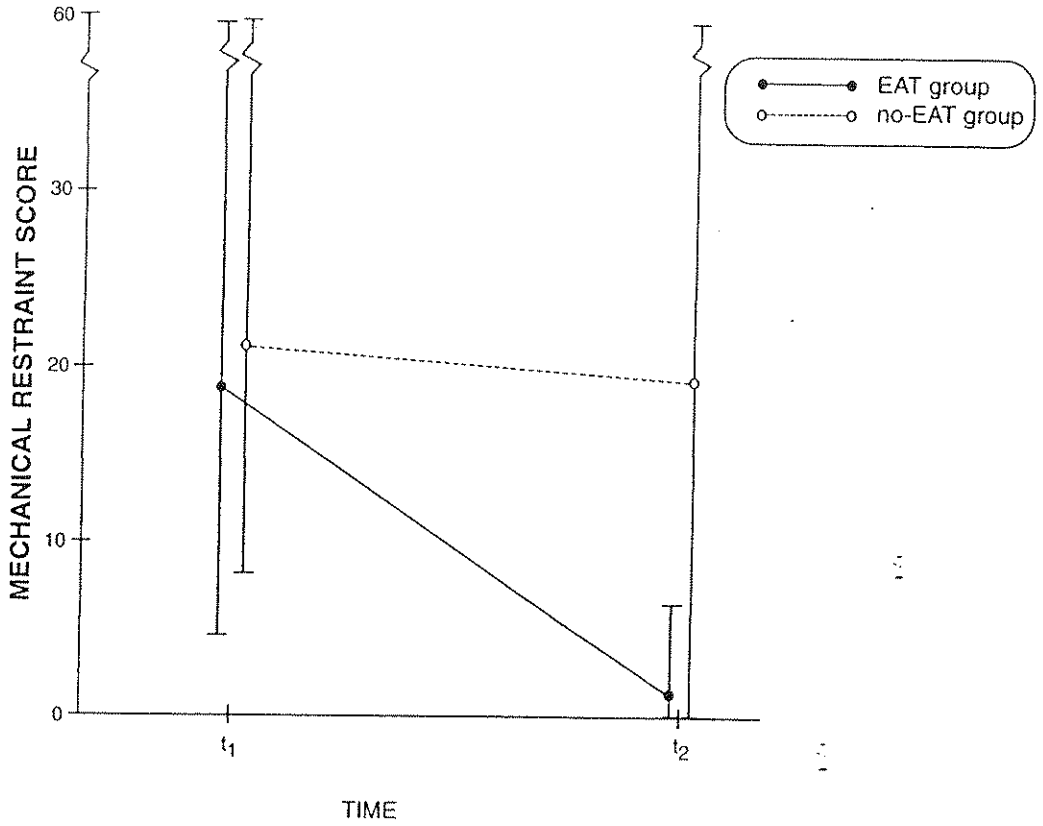


Fig. 1. Means and Ranges of Mechanical Restraint Scores for the EAT Group and the No-EAT Group at both time points.

ing its effects on SIB. Parents, regular caregivers, and teachers are now fully in charge of the treatment, while the case manager has been gradually withdrawn.

The no-EAT group did not remain in a treatment vacuum during the three years. While limiting the risk of inflicting tissue damage as much as possible, individuals of this group were exposed to a various categories of treatment, such as psychotropic treatments, behavior analytic treatments, and gentle teaching.

3. Results

Mechanical restraint scores, based on the IMRI, were used as the data for analysis. Fig. 1 shows the mean restraint scores and ranges of restraint scores for the EAT group and no-EAT group at both time points. At $t2$ a Wilcoxon matched-pairs signed-ranks test reveals a statistically significant difference in mechanical restraint scores favoring the EAT group, ($z = 2.24$, $p = .03$). The EAT group had a significantly lower mean restraint score at $t2$ than the no-EAT group. For the latter group, no significant difference was found between $t1$ and $t2$, ($z = .56$, $p = .57$).

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4. Discussion

A treatment using electrical aversive stimuli for severe, life-threatening SIB was effective in reducing the degree of mechanical restraints imposed by caregivers over three years. The change in degree of mechanical restraint imposed on an individual with mental retardation and severe SIB is, therefore, used as a measure of the effectiveness of treatment. It is assumed that an individual who has no restraints imposed on him or her exhibits, on average, less SIB than an individual mechanically restrained.

Across a period of approximately eight years, our group encompasses 39 individuals with severe SIB who are receiving or had received EAT. Treatment has yielded an overall effectiveness of 82%, defined as the joint number of individuals with whom EAT has been 1) initiated and continued, and; 2) withdrawn with full suppression of SIB. A restraint score was available for only eight individuals in the EAT group, due to an initiation of the present treatment with many individuals earlier than at *t*1, and for whom IMRI scores were not available. Similarly, other individuals with severe SIB were brought to our attention later than at *t*1.

We believe that the conclusion based on this study reflects only a conservative estimation of the true effect of EAT. Some support for this statement might be found in a meta-analysis (Didden et al., 1997), with EAT or contingent shock being one of the most effective interventions for severe problem behavior. Nevertheless, EAT should be employed only if less intrusive procedures have failed and, needless to say, only if consent has been obtained.

These results are at variance with those obtained in other studies reporting long-term effects. For example, Ricketts, Goza & Matese (1993), in a 4-year follow-up, found a loss of effectiveness to the extent that treatment with the individual with severe SIB had to be withdrawn. This difference may be explained by the fact that Ricketts et al. (1993) used a much milder stimulus than ours. The same finding, that is, a weak suppressive effect of the electrical aversive stimulus they used, has been reported by Williams, Kirkpatrick-Sanchez & Iwata (1993), and earlier by Worsham et al. (1992). It is, therefore, suggested that employing a relatively strong electrical stimulus to maintain suppression of severe and life-threatening SIB may be necessary.

There is much debate about the use of aversive stimuli as a treatment modality for severe and life-threatening problem behaviors (see for example, Mulick, 1990). Pivotal in the discussion on the acceptability of aversive stimuli is to what extent a treatment is experienced by the individual with severe SIB himself as being more or less aversive. It is our experience that many individuals who receive electrical aversive stimuli, once SIB is sufficiently suppressed, seem to feel more comfortable and happy when they are wearing the shock receiver rather than when the receiver is detached from the body (e.g., during showering and changing diapers). This observation is supported by the findings of Linscheid, Pejeau, Cohen & Footo-Lenz (1994).

It should be emphasized that EAT is a complicated procedure that should be

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employed by experts only. To mention but a few problems that may be encountered during the often extended course of treatment are that individuals may adapt to the intensity of the electrical stimulus, that self-restraint may emerge or may intensify, that individuals may show SIB at very low intensities that eventually results in tissue damage, etc.

Although the no-EAT group did not remain in a treatment vacuum during the period of three years, none of the treatments given to them had any significant effect on their degree of mechanical restraint.

It might be argued that conclusions are based on a relatively small group of participants. Although this is true, one should acknowledge that time investment for each single participant being treated with EAT ranges from 30 to 120 therapist hours, rendering studies with larger samples rather unlikely. Data were collected in a quasi-experimental design, that is, subjects were not randomly assigned to either the EAT or the no-EAT group, but matched retrospectively.

In conclusion, EAT might be an effective treatment for individuals with severe, life-threatening SIB, who are mechanically restrained to prevent them from inflicting serious injuries, and with whom other categories of treatment have failed.

Acknowledgment

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Side effects of contingent shock treatment

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Abstract

In this study, the side effects of contingent shock (CS) treatment were addressed with a group of nine individuals, who showed severe forms of self-injurious behavior (SIB) and aggressive behavior. Side effects were assigned to one of the following four behavior categories; (a) positive verbal and nonverbal utterances, (b) negative verbal and nonverbal utterances, (c) socially appropriate behaviors, and (d) time off work. When treatment was compared to baseline measures, results showed that with all behavior categories, individuals either significantly improved, or did not show any change. Negative side effects failed to be found in this study.
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Keywords: Contingent shock; Side effects; Collateral behavior; Punishment

Severe problem behaviors (e.g., self-injurious behavior [SIB] and aggressive behavior) can threat students' and staff members' health and well-being. Several $n = 1$, some $n > 1$ studies (Duker & Seys, 1996, 2000; Linscheid & Reichenbach, 2002; Ricketts, Goza, & Matese, 1992, 1993; Williams, Kirkpatrick-Sanchez, & Crocker, 1994), and meta-analyses (e.g., Didden, Duker, & Korzilius, 1997; Scotti, Evans, Meyer, & Walker, 1991) have demonstrated the superiority of contingent shock (CS) over other behavioral and nonbehavioral procedures (e.g., nonaversive procedures, pharmacology) in decelerating severe problem behaviors. In spite of these results, CS is often criticized in that it induces a number of negative side effects including increases in aggression, escape behavior, and negative emotional responses (for a review, see Lerman & Vorndran, 2002).

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Although several studies have mentioned the side effects of CS, few have systematically investigated these effects. Generally, it is reported that the positive side effects outnumber the negative side effects. For example, Matson and Taras (1989) reviewed 56 applied studies and reported that 96% of the side effects were positive (i.e., increased social behavior, increased activity levels, increased eye contact). Ball, Sibbach, Jones, Steele, and Frazier (1975) reported that individuals who were treated with CS became more affectionate and socially responsive. Mudford, Boundy, and Murray (1995) found their participants to be calmer, happier, and less clingy to people during treatment, as compared to baseline. Ricketts et al. (1992, 1993) reported that participants more often smiled and emitted happy vocalizations during CS treatment than during baseline. Also, distressed vocalizations (e.g., crying, whining) decreased during CS treatment. Linscheid, Pejeau, Cohen, and Footo-Lenz (1994) and Linscheid and Reichenbach (2002) found an increase of behaviors that may indicate a positive affective state (e.g., laughing, smiling, self-initiated toy play) during CS treatment, as compared to baseline. Negative side effects (e.g., increase of crying and whining) of CS failed to be mentioned in any study. Duker and Van den Munckhof (2007) demonstrated with five individuals who were treated with CS, that wearing a CS device lowered their heart rate, probably indicating lowered stress levels.

In this study, we addressed the side effects of CS treatment with a group of nine individuals who showed severe forms of SIB and aggressive behavior. Data were collected using a nonconcurrent, quasi-multiple baseline design across participants (Watson & Workman, 1981). Results were analysed using visual analyses conducted by seven clinicians.

1. Participants and setting

Participants were nine students (i.e., five boys and four girls) of the Judge Rotenberg Educational Center (JRC) in Canton, MA. Participants' chronological ages ranged from 8 to 30 years (M = 16.2, S.D. = 5.5) at the start of the study. All of them showed high frequencies and severe forms of SIB and aggressive behavior. Functional assessments were conducted to assess which factors might cause or maintain participants' target behaviors, revealing that the behaviors were either multiply controlled or controlled by unknown causes. Physicians had excluded medical causes of the target behaviors.

Each participant was consulted by a psychiatrist to assess his or her diagnosis. Preference assessment was conducted with all participants. Reinforcement procedures (e.g., differential reinforcement of other behaviors, differential reinforcement of alternative behaviors), and aversive procedures (e.g., token fines and reprimands) had failed to decelerate the participants' problem behaviors. Pharmacological treatments (e.g., antipsychotics, antidepressants) had been tried unsuccessfully in programs the participants attended prior to coming to JRC. Participants lived in JRC-staffed residential homes and attended JRC's day school program. Informed consent for the use of CS with the participants was obtained from their parent(s) or guardian(s). All treatment teams overseeing a participant's treatment program were headed by a doctoral level clinician who was responsible for writing a plan that listed specifically which behaviors would be treated with CS. In addition, JRC sought and obtained permission from the Bristol County, MA Probate Court for each participant involved to use CS to decrease their problem behaviors. Four participants received one-to-one coverage 24 hrs/day, two participants received coverage 16 h/day, and the other participants were treated on a one-to-three basis. For demographical information, see Table 1.

Table 1
Demographic information

Participant	Gender	Age	IQ/mental age	Diagnosis	Medication
1. S.S.	F	13;0	Moderate	Autism	–
2. T.F.	M	12;1	88	ADHD; ODD; IED	–
3. G.B.	M	15;11	81	Depressive disorder NOS; IED	–
4. A.J.	F	19;9	Full scale-80	Bipolar disorder; PTSD	–
5. T.E.	F	23;2	Mild	IED	–
6. E.L.	M	19;2	Full scale-75	Mood disorder NOS	–
7. K.F.	M	11;1	Mild	ODD	–
8. B.S.	M	18;4	Severe	PDD	–
9. R.S.	F	13;9	Severe	Autism	–

Note. M: male; F: female; age in years and months; ADHD: attention deficit hyperactivity disorder; ODD: oppositional defiant disorder; IED: intermittent explosive disorder; PTSD: post traumatic stress disorder; PDD: pervasive developmental disorder.

2. Device

Skin shocks were administered using the graduated electronic decelerator (GED) which is manufactured by JRC, consists of: (a) a remote control transmitter, which transmits an uniquely coded RF signal; (b) a receiver/stimulator, which receives a coded signal from the transmitter and generates a skin shock; (c) a battery pack; and (d) a set of electrodes, which are attached to participant's skin. Electrodes were either concentric (i.e., Tursky electrodes) or spread with two button electrodes separated by up to 6 in. One type of devices was used: the GED-1, which delivers a 2 s DC shock with a mean current of 15.5 mA (peak 30 mA), a voltage of 60 V, at a measured skin resistance of 4 $k\Omega/cm^2$. Devices generate a square wave at 83 pulses per second (pps). Depending upon the severity of the individual's problem behaviors, each participant wore one to five sets of electrodes at the same time, with the shock being delivered to only one of the set of electrodes as a consequence for a particular behavior.

3. Response definitions

Four mutually exclusive categories of target behaviors were defined: (a) positive verbal and nonverbal utterances (PVNU), such as appropriate smiling, dancing, singing or talking (e.g., "I am so happy," "Oh, yes!"); (b) negative verbal and nonverbal utterances (NVNU), such as crying, making whining noises, spitting, stamping feet, smearing faeces, screaming, swearing, making obscene gestures, shrugging shoulders, uttering racial comments, making negative facial expressions (e.g., rolling eyes), and imitating others; (c) socially appropriate behaviors (SAB), such as raising one's hand in the classroom, greeting others, politely asking the teacher for help, following directions, and appropriately responding to the teachers' and staff members' instructions; and (d) off task (OT) behaviors, such as placing one's head down on the table, rejecting academic tasks, and turning one's head away when a staff member offers beverages or edibles. Target behaviors were selected by interviewing participants' teachers and staff members, record reviews, and direct observation.

4. Recording

During baseline and treatment, participants were videotaped for 10 min, 5 days per week. Participants were videotaped at randomly chosen points in time, but always during times when

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teachers and staff members were not applying reinforcing contingencies. Using a 10-s partial interval recording system, observers assigned each target behavior to one of the above four behavior categories. All target behaviors that occurred during videotaping were assigned to a category, even when behaviors occurred simultaneously. The number of video-taped 10-min sessions for the participants across phases of baseline and treatment ranged from 24 to 51 ($M = 30.22$, $S.D. = 8.15$).

5. Reliability of recording

Interrater agreement between two observers, one of whom was kept naive as to the purpose of the study, was conducted in 26% of the recording sessions, which were approximately equally distributed across baseline and treatment phases. Agreement was calculated by dividing the number of agreements by the number of agreements plus disagreements, multiplied by 100. Interrater reliability ranged from 93.48 to 97.76% ($M = 95.48$, $S.D. = 1.85$). Percentages were then converted into a kappa coefficient (Cohen, 1960), a statistic that takes chance agreement into account. Kappa scores ranged from .92 to .97 ($M = .94$, $S.D. = .19$).

6. Procedure

6.1. Baseline

During baseline, CS treatment was withheld. During this phase, (a) differential reinforcement of other behaviors with intervals ranging from 5 min to 7 days, (b) a token system for completing academic tasks and/or for intervals of appropriate behavior, and (c) a response cost system were in effect. Moreover, mild aversive procedures and response contingent restraints were in effect. Duration of mechanical (e.g., mitts, restraint chair) or physical restraint (i.e., holding arms, legs, and upper part of the body) could extend up to 6 h, depending upon whether participant's problem behaviors recurred during the restraint. The above procedures were carried out on a 365 days per year, 24 h per day basis, and were administered in all of each participant's settings (i.e., in the classroom, during transportation, and in the residential home).

6.2. Treatment

While the above procedures continued, SIB and aggressive behavior were immediately followed by a single administration of an electrical skin shock. Following this, the staff member or teacher involved would inform the participant verbally and briefly why the shock had been administered. Then, if necessary, the participant was prompted to continue his/her task. Finally, the staff member rotated the electrodes a few centimeters away from their previous locations on participant's body and recorded the time of shock administration.

7. Design

Data were collected using a nonconcurrent quasi-multiple baseline design across participants (Watson & Workman, 1981), in which the length of the baseline phase was determined on a random basis. For each participant, the date at which the treatment phase began was determined by the date at which JRC happened to obtain court approval for skin-shock treatment for that participant.

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8. Results

Table 2 shows *M*, S.D., and range of participants' PVNU, NVNU, SAP, and OT percentages during baseline and treatment. Figs. 1–4 display in graphical form the percentages of these behaviors per 10-s interval for all participants. Graphs are ordered per

Table 2
Means, ranges, and standard deviations of PVNU, NVNU, SAB, and OT percentages for 10-min intervals during baseline and treatment

Participant	Baseline				Treatment			
	No. of intervals	*M*	Range	S.D.	No. of intervals	*M*	Range	S.D.
PNVU								
S.S.	3	1.01	0.00–3.03	1.75	45	7.81	0.00–55.00	13.73
T.F.	7	7.29	0.00–20.00	6.74	19	5.2	0.00–24.14	6.75
G.B	11	2.89	0.00–26.67	7.93	17	1.96	0.00–28.57	6.89
A.J.	4	15.68	6.00–31.67	11.12	22	4.67	0.00–26.67	2.87
T.E.	10	5.97	0.00–15.00	4.61	20	2.98	0.00–10.17	3.46
E.L.	5	1.38	0.00–3.70	1.52	22	1.97	0.00–29.41	6.23
K.F.	5	4.84	1.69–11.11	3.69	17	5.9	0.00–17.50	5.85
B.S.	11	4.00	0.00–11.59	3.88	30	13.66	0.00–43.33	14.16
R.S.	14	8.25	0.00–27.12	8.04	11	11.15	0.00–33.33	9.56
NVNU								
S.S.	3	31.6	1.61–56.82	27.91	45	13.70	0.00–95.59	20.30
T.F.	7	9.00	0.00–36.67	13.28	19	0.79	0.00–3.33	1.16
G.B	11	1.70	0.00–15.25	4.55	17	0.52	0.00–7.14	1.75
A.J.	4	6.59	0.00–18.00	8.12	22	2.19	0.00–8.33	2.76
T.E.	10	0.51	0.00–3.39	1.15	20	0.38	0.00–4.00	1.02
E.L.	5	0.67	0.00–3.33	1.49	22	0.00	0.00–0.00	0.00
K.F.	5	17.04	0.00–41.30	15.58	17	4.60	0.00–20.00	5.95
B.S.	11	0.45	0.00–3.33	1.08	20	0.17	0.00–1.67	0.51
R.S.	14	13.95	0.00–32.76	12.68	11	3.33	0.00–12.67	4.35
SAB								
T.F.	7	2.60	1.39–5.00	1.39	19	0.78	0.00–20.00	6.74
G.B	11	1.70	0.00–15.25	4.55	17	4.75	0.00–25.93	7.16
A.J.	4	1.00	0.00–4.00	2.00	22	2.19	0.00–8.33	2.76
T.E.	10	0.00	0.00–0.00	0.00	20	0.13	0.00–2.50	0.56
E.L.	5	2.94	0.00–6.67	2.65	22	3.87	0.00–25.00	7.20
K.F.	5	2.36	0.00–6.78	2.84	17	8.81	0.00–20.93	7.47
B.S.	11	0.15	0.00–1.67	0.50	20	0.00	0.00–0.00	0.00
R.S.	14	27.20	3.39–47.37	12.61	11	11.54	0.00–26.51	9.53
OT								
S.S.	3	41.82	30.30–50.00	10.27	45	7.47	0.00–71.67	16.90
T.F.	7	43.61	19.05–76.67	22.18	19	13.59	1.67–35.48	8.34
G.B	7	67.52	0.00–100.00	40.00	17	6.38	0.00–44.62	11.05
A.J.	4	92.06	84.75–100.00	6.37	22	29.55	1.59–100.00	23.77
T.E.	10	3.37	0.00–10.00	3.56	20	2.47	0.00–12.00	3.04
E.L.	5	8.40	1.82–17.02	5.50	22	2.94	0.00–24.13	5.30
K.F.	5	59.90	46.15–84.75	16.71	16	34.99	6.00–83.87	23.14
B.S.	11	31.55	7.14–48.15	11.06	20	21.69	1.67–50.00	15.43
R.S.	14	27.20	3.39–47.37	12.61	11	11.54	0.00–26.51	9.53

Note. *M* = mean; S.D. = standard deviation.

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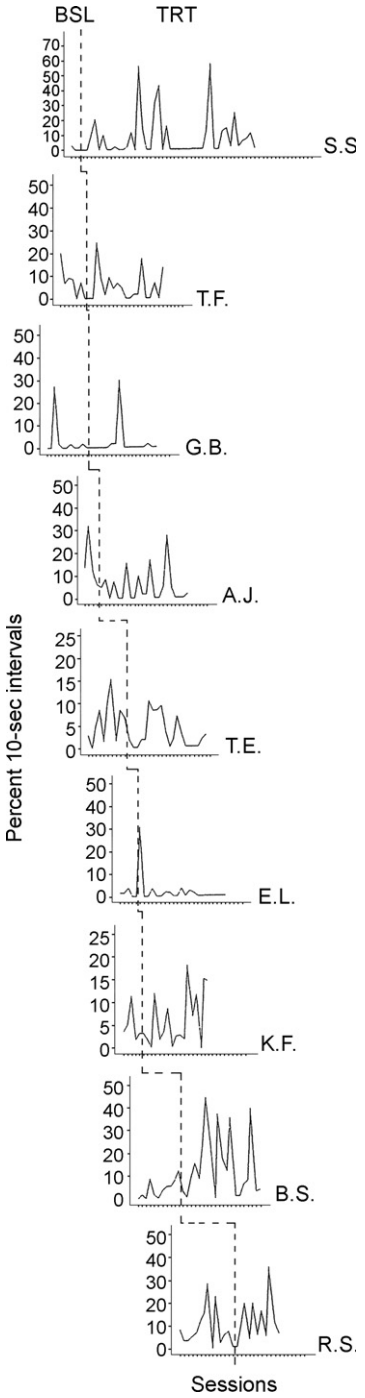


Fig. 1. Percentage PNVU per 10-s intervals during baseline and treatment sessions.

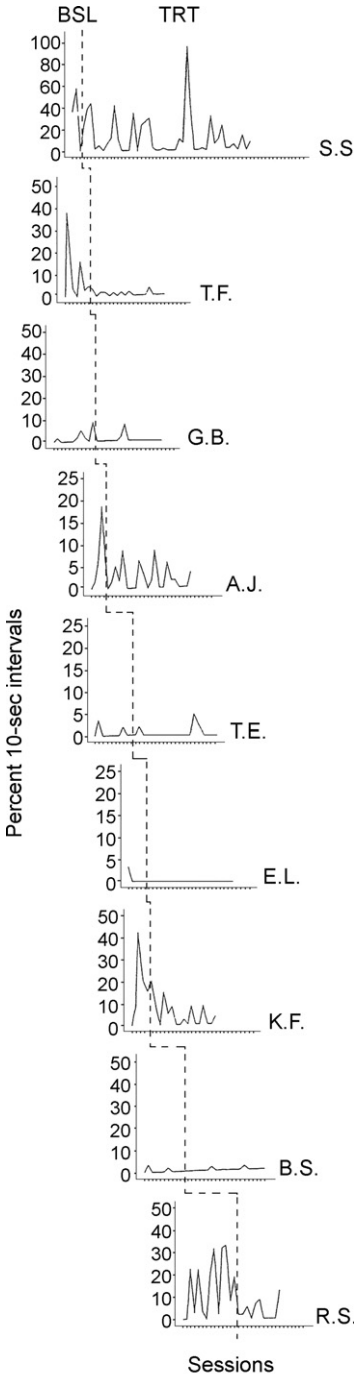


Fig. 2. Percentage NVNU per 10-s intervals during baseline and treatment sessions.

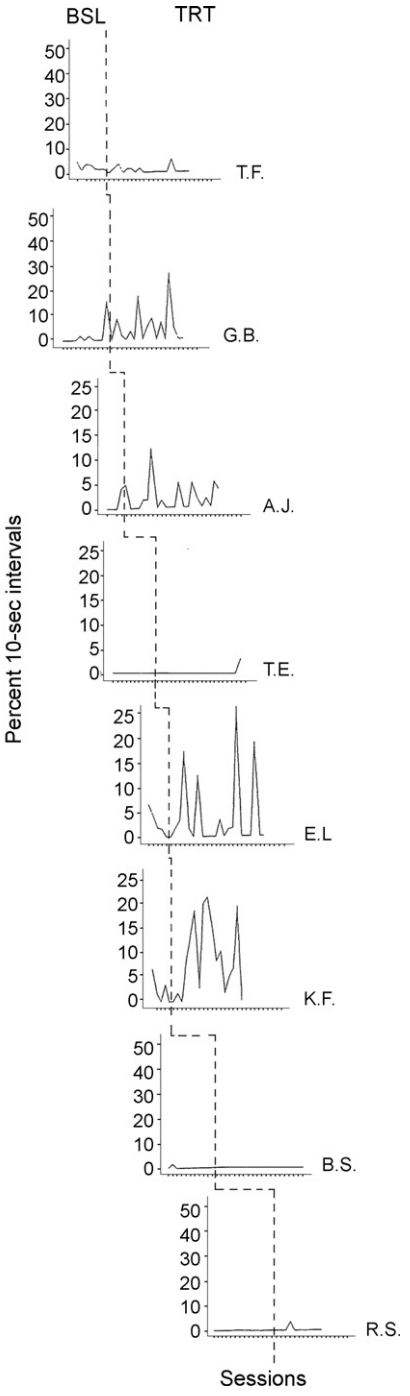


Fig. 3. Percentage SAB per 10-s intervals during baseline and treatment sessions.

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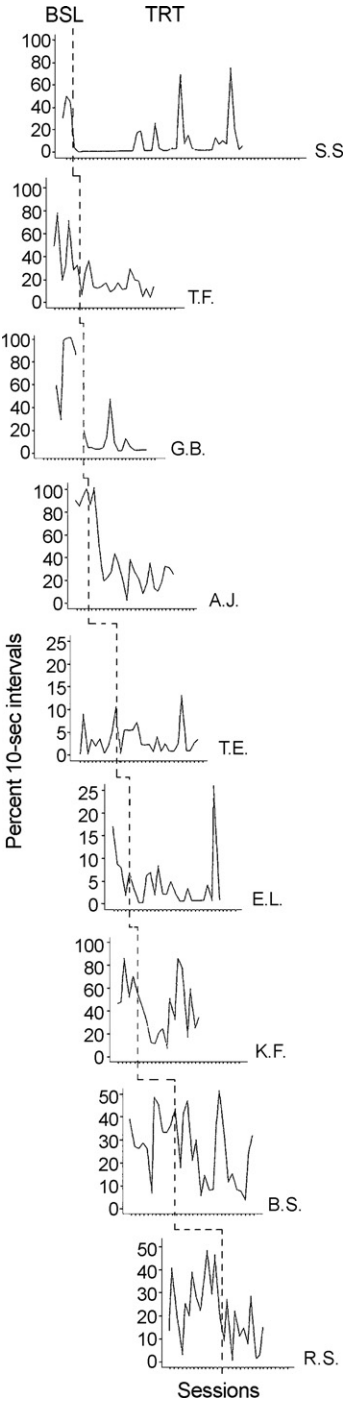


Fig. 4. Percentage OT per 10-s intervals during baseline and treatment sessions.

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behavior category and portray the character of the multiple baseline design in which the data were collected.

Data were examined on an individual basis, using visual analysis. Seven clinicians independently judged, for each graph in Figs. 1–4, whether there was a significant change or not in percentages between baseline and treatment phase. For all PVNU graphs, a mean agreement of 78% across clinicians was obtained. Participant B.S. significantly increased (100% agreement) the percentage of intervals of PVNU, when treatment phase was compared to baseline phase. No changes were recorded for the other participants. For all NVNU graphs, a mean agreement of 92% across clinicians was obtained. Participants T.F. (100% agreement), A.J. (71% agreement), K.F. (100% agreement), and R.S. (100% agreement) significantly decreased the percentage of intervals of NVNU, when treatment phase was compared to baseline. No changes were recorded for the other participants. For all SAB graphs, a mean agreement of 91% across clinicians was obtained. Participants G.B. (71% agreement), E.L. (100% agreement), and K.F. (100% agreement) significantly increased the percentage of intervals of SAB, when treatment phase was compared to baseline phase. No changes were recorded for the other participants. For all OT graphs, a mean agreement of 89% across clinicians was obtained. Participants T.F. (86% agreement), G.B. (100% agreement), A.J. (100% agreement), and R.S. (86% agreement) significantly decreased the percentage of intervals of OT, when treatment phase was compared to baseline phase. No changes were recorded for the other participants.

9. Discussion

In this study, we addressed the occurrence of potential side effects of CS treatment with a group of nine participants, who showed severe forms of SIB and aggressive behavior. In all behavior categories (i.e., PVNU, NVNU, SAB, and OT) participants either significantly improved, or did not show any change, when the treatment phase was compared to baseline. Negative side effects were not observed. These results are supported by findings of Ball et al. (1975), Linscheid et al. (1994), Linscheid and Reichenbach (2002), Mudford et al. (1995), and Ricketts et al. (1992, 1993).

Some limitations may affect the conclusions of this study. First, no statistical analysis was conducted, due to the short baselines employed with some of the participants. Some forms of SIB and aggressive behavior of these participants were of such severity, that CS treatment had to be initiated immediately following court permission. With pre-determined baseline lengths, reactive intervention as a possible invalidating factor would have been controlled. As an alternative, visual analysis was conducted by seven clinicians, whose agreement ranged from 57 to 100%.

Second, analyses failed to be conducted at the group level across behavior categories, because the four categories of behavior were not applicable in the same degree to all participants. For example, participant S.S. was a girl with severe mental retardation, and who, by definition, failed to show any form of SAB. Participant E.L., who was a man with normal intelligence, hardly showed any form PVNU during his academic work, because he was working on his tasks with steady concentration most of the time. These observations suggest that if side effects are present during CS treatment, the specific forms may differ across individuals.

Third, participants may have been aware of the video recording, which may, therefore, have caused bias in data collection. However, participants were naïve as to the purpose of the study. In addition, the participants were used to being video-recorded, because all students and staff members were routinely monitored by video cameras in school and residential houses 24 h per day.

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The objection that CS should not be used due to associated negative side effects, fails to be inconsistent with the results of this study. By contrast, according to previous research, the present study demonstrates that positive side effects are probably more common than negative side effects.

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Treatment of Aggression with Behavioral Programming that Includes Supplementary Contingent Skin-Shock

Matthew L. Israel, Nathan A. Blenkush, Robert E. von Heyn, and Patricia M. Rivera

Abstract

Behavioral treatment of aggression with contingent skin shock (CSS) has been investigated in relatively few studies and never with cognitively typical individuals. We evaluated CSS during a 3-year period with 60 participants, half to two-thirds of whom functioned at normal or near-normal cognitive levels. Sixty individual charts, arranged in a multiple baseline across participants display, reveal clearly the effectiveness of the treatment. When end-of-baseline data were compared with end-of-treatment data, CSS, as a supplement to positive programming, showed effectiveness (defined as a 90% or greater reduction from baseline) with 100% of the participants. This compares favorably with positive behavior support procedures, which, according to the 1999 treatment outcome review by Carr at al., achieved that effectiveness standard with only 55.5% of the cases (Carr et al., 1999). Higher functioning participants showed from 2 to 6 times more reduction than did lower functioning participants. Psychotropic medications were reduced by 98%, emergency takedown restraints were reduced by 100%, and aggression-caused staff injuries were reduced by 96%. As a result of the treatment, 38% of participants no longer required CSS and some returned to a normal living pattern.

Key words: aggression, contingent shock, skin-shock, punishment

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Individuals who exhibit high frequency and/or high intensity aggressive behaviors are often treated with psychotropic medication and behavioral procedures. Unfortunately, psychotropic drugs have proven ineffective in treating the aggression of many individuals, including all of the participants in the present study. They also sometimes produce unfortunate side effects such as sedation, severe weight gain, tardive dyskinesia, neuroleptic malignant syndrome, etc.

The behavioral procedures employed in current clinical practice to treat aggression are usually limited to "positive-only" procedures such as the manipulation of positive reinforcers, the arrangement of antecedents and setting events, provision of educational procedures, and the use of decelerating procedures other than physical aversives. If such procedures prove to be insufficiently effective, the individual is likely to continue to receive high doses of psychotropic medication, may be subjected to substantial amounts of restraint or isolation, and/or may be transferred to a highly restrictive environment (Foxx, 2003).

Contingent skin-shock (CSS), when used as a supplement to other behavioral procedures, has proven effective in treating various problem behaviors that were otherwise intractable. Most of the CSS treatment studies that have been published since 1965 have involved self-injurious behaviors (e.g., Salvy, Mulick, Butter, Bartlett, & Linscheid, 2004; Linscheid & Reichenbach, 2002; Duker & Seys, 1996; and Mudford, Boundy, & Murray, 1995). Other behaviors treated have included (ordered according to the frequency with which the topic has been reported) aggression (e.g., Foxx, McMorrow, Bittle, & Bechtel, 1986); ruminating and/or vomiting (e.g., Wright, Brown, & Andrews, 1978; Cunningham & Linscheid, 1976; Toister, Condron, Worley, & Arthur, 1975; Browning, 1971; Kohlenberg, 1970), auditory hallucinations (Turner, Hersen, & Bellack, 1977; Alford & Turner, 1976; Bucher & Fabricatore, 1970), destruction (e.g., Foxx, McMorrow, Bittle, & Bechtel, 1986; Bucher & King, 1971; Birnbrauer, 1968) screaming (Lebow, Gelfand, & Dobson, 1970; Hamilton & Standahl, 1969), obsessive behaviors (Anderson & Alpert, 1974); wrong answers (Kircher, Pear, & Martin, 1971; Birnbrauer, 1968), self-

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induced seizures (Wright, 1973), stereotypic rocking (Baumeister & Forehand, 1972), and noncompliance with a direction to approach (Lovaas, Schaeffer, & Simmons, 1965).

With respect to the use of CSS to treat aggression, we found nine original published studies but none in the last 13 years. The topographies treated included aggressive biting (Foxx, Zukotynski, & Williams, 1994), hair-pulling and aggressive/destructive episodes (Foxx, Bittle, & Faw, 1989), pinching, kicking, hitting, and hair-pulling (Foxx, McMorrow, Bittle & Bechtel, 1986), assaults toward others (Ball, Sibbach, Jones, Steele, & Frazier, 1975), biting, kicking, and choking (Brandsma & Stein, 1973), physically striking another person, (Browning, 1971), hitting, kicking, biting, spitting, and verbal threats to aggress (Ludwig, Marx, Hill, & Browning, 1969), biting, (Birnbrauer, 1968) and aggression toward a brother (Risley 1968).

The CSS literature has limitations. First, most papers report CSS use with only one or relatively few individuals. The largest study was by Duker and Seys (1996) who reported CSS use with 12 participants.

Second, a variety of shock delivery systems with varying shock intensity and durations have been used. For example, within the past 21 years, shock delivery systems have included the HSP'3012 (Duker & Seys, 1996), Therapeutic Shock Device (TSD) (Mudford, Boundy & Murray, 1995), Hot Shot Power Mite (Williams, Kirkpatrick-Sanchez, & Iwata, 1993), Self-injurious Behavior Inhibiting System (SIBIS) (Linscheid, Iwata, Ricketts, Williams, & Griffen, 1990), and Tritronics A1-70 (Foxx, McMorrow, Bittle, & Bechtel, 1986). The differing devices and often incomplete descriptions of their parameters make it difficult to compare the effect of CSS treatment across studies or individuals.

Third, most CSS studies have been with participants who functioned at a relatively low cognitive level and who had diagnoses such as severe mental retardation (MR) and related disabilities. Few studies have involved participants with normal or near-normal cognitive levels who had diagnoses such as conduct disorder, bipolar disorder, oppositional defiant disorder, and impulse control disorder.

In this paper we report data and procedures that address these issues. We treated aggression in 60 individuals with widely differing levels of cognitive functioning for periods of up to three years, using positive behavioral procedures supplemented with CSS. We report the immediate effects of the introduction of CSS on behavior frequency, the overall reductive effect of CSS, and its effect on ongoing accelerations or decelerations. We compare the reductive effect of CSS with the reductive effect of positive behavior support in treating aggression. We describe the differential effect of CSS treatment on participants with differing levels of cognitive functioning. And we describe the effect of CSS treatment of aggression on the need for psychotropic medication, on the need for emergency takedown restraint, and on aggression-caused staff injuries.

METHOD

Participants

A total of 60 (41 male and 19 female) residents, who were enrolled at the Judge Rotenberg Center (JRC) in Canton, MA participated in the study. The median age was 18 (range 9-36). Prior to enrolling in JRC, the participants had attended a median of 4 (range 0-42) special needs day, residential, psychiatric or correctional programs and had been prescribed, at various points in their history, a median of 6 (range 1-21) different psychotropic medications. Although treatment histories varied, all participants in this study had been rejected by, unsuccessfully treated in, or expelled from other settings that had used a combination of positive-only behavioral interventions and psychotropic medications.
Demographic information for the participants is presented in Table 1. Note that the total of Other

Diagnoses (81) exceeds the number of participants (60) because many participants had multiple diagnoses. Forty-seven percent did not have an MR diagnosis.

Table 1
Participant demographic information including frequency count of all assigned diagnoses (N=60)

		Number	%
Gender			
male		41	68
female		19	32
	Total	**60**	**100**
Age			
<10		1	1.7
10-15		12	20.0
16-20		40	66.7
21-25		5	8.3
26<		2	3.3
	Total	**60**	**100**
Diagnosis re Mental Retardation Status			
No Mental Retardation		28	46.7
Mild		11	18.3
Moderate		7	11.7
Severe/Profound		14	23.3
	Total	**60**	**100**
Other Diagnoses			
Autism		16	
Mood Disorder NOS		10	
Intermittent Explosive Disorder		10	
Conduct Disorder		8	
Oppositional Defiant Disorder		8	
Bipolar Disorder		8	
Pervasive Developmental Disorder		6	
Attention Deficit Hyperactive Disorder		4	
Impulse Control Disorder		3	
Disruptive Behavior Disorder		2	
Antisocial Personality Disorder		1	
Borderline Personality Disorder		1	
Depressive Disorder NOS		1	
Mental Disorder NOS		1	
Schizophrenia		1	
Tourette's Disorder		1	
	Total	**81**	

The participants were all of the JRC residents, for whom CSS had been added to their programs at some point during the 3-year period from June 1, 2003 to May 31, 2006 and whose enrollment had not been significantly interrupted by absences. During this period a total of 65 residents met this criterion. Four were excluded because of logistical difficulties in obtaining written consent. One guardian did not consent to participate. Another 7 residents had CSS added to their programs during this period; however, their data were excluded from this study because of long absences from the program due to medical needs or other circumstances.

CSS was not considered for each participant until a variety of positive-only procedures had been tried at JRC and had been found or judged to be insufficiently effective in light of the clinical needs of each participant. The median number of weeks during which positive-only procedures alone were tried, prior to the introduction of CSS, was 38 (range 5-108). In a few cases, where the aggressive behavior was judged to be so extreme or problematic that even a single occurrence could be extremely dangerous, CSS was started shortly after the participant was admitted to JRC.

Psychotropic medication

Forty-eight of the 60 participants were receiving a median of 2 (range 1-6) psychotropic medications when they enrolled at JRC. Under the direction of a consulting psychiatrist, these medications were gradually reduced over a median of 5 (range 0-42) months. Most participants were weaned from psychotropic medication during the baseline phase. In a few cases the weaning extended into the treatment phase.

Safeguards

The following safeguards were in effect prior to the use of CSS: (a) The parent/guardian gave informed written consent to the use of CSS. (b) If the participant was of school age, CSS was placed in his or her Individual Education Plan. (c) A doctoral level clinician, with training in behavioral psychology, headed the participant's treatment team and composed a treatment plan that included the option to employ CSS. (d) A physician and, where appropriate, a neurologist and/or cardiologist certified the absence of medical contraindications to the use of CSS for each participant. (e) A psychiatrist certified the absence of psychiatric contraindications to the use of CSS for each participant who had a mental illness diagnosis. (f) An internal peer review committee reviewed the plan and deemed it appropriate. (g) A human rights committee composed of JRC parents, as well as community members unaffiliated with JRC, approved the plan. (h) A Massachusetts Probate Court judge authorized the treatment plan through a "substituted judgment" petition in an individual court hearing in which the participant was represented by his or her own court-appointed attorney. (i) The court-appointed attorney retained his or her own psychologist to provide advice concerning the proposed treatment.

Additional safeguards were in effect after the treatment plan went into effect. Reports on the participant's treatment status were submitted to the Probate Court every 3 months and the judge held a formal review each year. In all cases in which CSS was used for 3 or more years, a special committee composed of JRC staff and consultants, including two independent clinicians unaffiliated with JRC, reviewed the treatment and its results to determine if it should continue.

Setting

All participants lived in apartments or homes operated and staffed by JRC and were transported to and from JRC's day program where they received treatment, education, and vocational instruction and opportunities. During the first 4 months of the 3-year period reported here, participants attended the day program 5 days per week. During the remaining 32 months of the period, participants attended the day

program 7 days per week. The same treatment procedures were in place and carried out consistently in the school building, in the residence, on field trips, and during transportation to and from school.

The participants' programs in both day and residential settings were monitored directly by on-scene supervisors, as well as remotely by supervisors who watched live and recorded video and audio, on a sampling or continuous 24/7 basis. Video cameras and microphones were mounted in all appropriate locations of the school and residences. This equipment allowed the supervisors to monitor from a central office, in real time over the Internet, all activities in the participants' classrooms and residences.

Behavior categories and topographies

A supervising clinician, with a caseload of 15 to 20, oversaw each participant's program with the assistance of other members of the treatment team, such as the teacher, residence supervisor, and a case manager. The behavior category treated was termed "aggression," meaning any behavior that inflicted harm on other persons. Because there are an unlimited number of topographies that a participant could use to inflict harm on others, and because new topographies could emerge abruptly, each participant's clinician identified the topographies that were currently in the participant's repertoire and was authorized, in the court-approved treatment plan, to identify and add other topographies to the treatment plan as soon as they were displayed.

Examples of topographies within the aggression category included the following: hit others, bite others, kick others, throw objects at others, head butt others, choke others, and pull hair of others. The topographies treated included not only the ultimate aggressive behaviors themselves, but also antecedent behaviors, attempts and threats to execute the behavior, shaped-down (vestigial) versions that were displayed during the deceleration of the behavior, as well as initial and intermediate members of the chain that included the ultimate aggressive action.

For all participants, aggression was only one of several behavior categories that were treated with CSS at the same time. The other categories that were treated depended on the participant's treatment plan and could include health dangerous (self-injurious), destructive (e.g., breaking windows, desks, computers), noncompliant (e.g., refusal to follow a request), and major disruptive (e.g. swearing, yelling, disrobing in public, etc.), behaviors. Data for the treatment of these other behavior categories are not included in this report.

Data collection

Frequency data was collected by direct care staff 24 hours per day, 7 days per week. Each aggressive topography was tallied as it occurred, using recording sheets that were segmented by hour and that accompanied the participants in all activities. Hand counters were used to count high frequency behaviors. Aggressive behavior sometimes occurred in episodes in which several aggressive actions occurred within a short period of time. In these cases, the staff member administered one application of CSS to consequate the entire episode, but tallied each individual aggressive behavior. The total number of aggressive behaviors exhibited each day was entered in a database and displayed on daily, weekly, monthly, or yearly software charts that were updated daily and made available to clinicians, teachers, and parents through a computer network. Total CSS applications were recorded separately and totaled across all treated behaviors, but were not separated by behavior categories such as aggression.

To evaluate the effects of CSS treatment of aggression on participants of differing functioning levels we classified students by functioning level and compared the reductive effect of the treatment on the two groups. To obtain information about psychotropic medication use, emergency takedown restraints, and aggression-caused staff injuries we reviewed the participants' records as well as records of staff injuries.

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Materials

CSS was administered by means of a skin-shock device called the Graduated Electronic Decelerator (GED). GEDs of two strengths were used—the GED-1 and GED-4. The GED-1 produced an average current of 15 mA RMS and an average voltage of 60 V RMS when applied to a resistor of 4 kΩ (typical skin resistance for the GED-1). The electrical stimulus was a preset, 2 s train of direct current square waves with a duty cycle of 25% and a pulse repetition frequency of 80 pulses per second. The GED-4 produced an average current of 41 mA RMS and an average voltage of 66 V RMS when applied to a resistor of 1.6 kΩ (typical skin resistance for the GED-4). The other parameters of the GED-4 were identical to those of the GED-1.

Each GED system was comprised of a remote control transmitter, a shock generator (the GED device itself), a battery and an electrode. The transmitter, a SECO-LARM (model SK-919TD2A) two-channel RF transmitter, operated at 315 MHz and transmitted a uniquely coded signal to the receiver which was worn by the participant. The transmitter was housed in a lexan box (104 mm x 76 mm x 38mm) with the participant's name and photo on the outside.

The shock generator consisted of a receiver (SECO-LARM model SK-910) set to the same code as the transmitter, a shock controller circuit board that created the shock stimulus, and a stimulation-indication beeper (Mallory piezoelectric ceramic buzzer model PLD-27A 35W). The shock generator was housed in a lexan box (140 mm x 89 mm x 38 mm) and the unit weighed 269 g.

A 12 V rechargeable nickel metal hydride battery pack (Panasonic P/N HHR-AAB 2000 mAh) provided power to the shock generator and was housed in a lexan box with the same dimensions as those of the shock generator. The battery unit weighed 397 g. The battery was attached by Velcro to the shock generator and connected to it electrically by a short cable (Hirose Electric Co., Ltd., Part # H0063-ND). The battery and shock generator were both carried in a back pack or fanny pack worn by the participant. A cable (Hirose Electric Co., Ltd., Part # H0063-ND) connected the shock generator to the electrode. Each electrode was attached to one of several pre-approved locations, typically the arms, legs, or torso. The electrode and connecting cable were hidden by the participant's clothing.

The electrodes employed during the 3-year period were of two types: (1) a "concentric" electrode which consisted of a stainless steel button (diameter 9.5 mm, thickness 3.25 mm) surrounded by a stainless steel ring (outer diameter 21.5 mm, inner diameter 16.5 mm, thickness 3.25 mm) with 2.35 mm between the outer edge of the button and the inner edge of the ring; or (2) a "distanced" electrode consisted of two stainless steel buttons (diameter 9.5 mm, thickness 3.25mm) mounted up to 15.24 cm apart on flexible nonconductive material. During the 3-year period covered in this report, the vast majority of the participants wore distanced electrodes.

Each participant wore from one to five GED sets (each consisting of battery, shock generator, and associated electrode), depending on the decision of the participant's clinician as to the following: (a) whether it was necessary to consequate attempts by the participant to remove the equipment or interfere with the application; and/or (2) whether the participant would otherwise be able to defeat much of the effect of the CSS by tensing the muscles in the affected area prior to the application. Each remote control unit sent a signal to only one particular GED shock generator and that shock generator was connected to one electrode on the participant's body. When a participant wore more than one GED set, the therapist possessed a separate remote control for each set. In these cases, on any given application the participant did not know which electrode would deliver the skin-shock (i.e., which remote control device the staff member would employ). Electrodes were rotated to different skin locations at the end of each hour and after a skin-shock was applied.

Procedure

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There were two phases, baseline followed by treatment.

Baseline (Positive Programming).

Upon admission, functional assessments were completed for each participant. These suggested functions that were varied among individuals and were sometimes multiple and unknown.

To take account of the various possible functions, all environments and staff procedures were designed so that regardless of what event or events might function as a reinforcer on any given instance of the behavior, inadvertent or deliberate reinforcement of undesired behaviors would be avoided or minimized. In particular, systems were set up, and staff were trained, to insure that (a) any inadvertent reinforcement from positive or negative attention would be minimized or avoided whenever problem behaviors occurred; (b) any escape from demands that inevitably had to occur after a problem behavior was displayed would be minimized or avoided; and (c) desired tangible items or activities would never be arranged or allowed as the immediate consequence of a problem behavior. All participants were taught how to gain attention, escape from work, and obtain desired items or activities through appropriate and easily executed behaviors.

The participant's clinician reviewed daily behavior frequencies and frequency trends over time. As the clinicians prescribed and adjusted combinations of antecedent, reinforcement, extinction, response cost, and other procedures, they were able to see the effects of these changes in the charted data and make compensating adjustments when required. This amounted to an ongoing, *in vivo* functional analysis.

During the baseline phase, a variety of positive programming procedures were employed to decrease the aggressive behavior and to teach alternative desired behaviors. Each participant had DRO/DRA contracts in which, if the participant avoided displaying the problem behaviors during a certain period of time or activity, and also displayed desired behaviors in their place, reinforcers would be earned. Typically, each participant had multiple overlapping contracts covering different stimulus situations and periods (transport, overnight, less-than-a-day length, multiple-day length, etc.). The length of the contracts was gradually lengthened whenever possible. When a participant passed (i.e. met the conditions of) a contract, he/she was given points, tokens, or immediate access to desired items or activities. By passing a sufficient number of contracts, students could advance to higher level classrooms and residences with more privileges, gain more independence, and/or earn a part-time or full-time paid job inside or outside JRC.

Participants also received points, tokens, and other reinforcers on an intermittent basis throughout the day (essentially on an intermittent, momentary DRA schedule) provided they were "on contract" and engaging in appropriate behavior at the time the reinforcer was delivered.

Points, tokens, and direct access to reinforcers could also be earned by learning new academic, self-care and vocational skills and by responding appropriately to programmed stimuli, sometimes designed to represent stimuli that triggered problem behaviors, presented at various points during the day.

Points and tokens could be turned in for access to one or more of the following: money (participants could earn as much as $30 per week); field trips; the Reward Corner of the classroom; the Big Reward Store, which was an arcade-type room with pool table, pinball machines, video games etc.; the Internet; the Contract Store, which was a retail "store" with a variety of items for sale; items in the Classroom Reward Box; weekly field day activity, including barbecue and other desired activities; extra phone calls to parents and friends; opportunity to watch TV, play video games, or listen to music using entertainment consoles in the participants' bedrooms and living rooms; etc.

Other procedures included functional communication training, training in social skills, self-instruction in academic skills using personal computers as teaching machines (Skinner, 1958), and

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vional training. Hi gh-functioning participants were given behavioral c ounseling, self-management ting, a course in be hav ral psychology presenting a simplified version o f the concepts presented in Sk er's "Science and H n Behavior" (Skinner, 1953), and weekly beha avioral chart shares with other pa ipants/students.

Every item or a ctivi that the participants might enjoy was used as a contingent reward to en rage desired beha vior. desired behavior resulted in money or point f ines and/or a loss of pri ges previously ea rned. tremely dangerous behaviors were contained using emergency restraint an otective equipment. In me cases, mechanical restraint was employed to insure the participant's saf

Tr ent (Added CSS).

In this phase, all o the positive procedures employed during the base line phase continued to be used adjusted by the c linicians; however, all topographies listed under th e aggression category were now to "consequated" with a single GED application as soon after they oc urred as possible. The norm procedure for admi nistering a GED application required the staff mem nber to enlist a second staff mem to insure that (a) th e person about to administer the GED had selected the correct recording sheet for th participant, (b) the topography that had just occurred (or which was st ill occurring) had been pre-identified on that recording sheet as being a treatment target, (c) the consequence (GED) was the correct consequence for that topography, and (d) the person administering had selected the correct remote control for the participant. These requirements introduced a slight delay in the admin istration of the consequence; however, the gains in insuring proper execution of the procedure were judged to be worth the slight delay involved.

Some participants wore more than one GED, and up to a maximum of five GEDs, if it was necessary to consequate attempts by the participant to remove the equipment or interfere with the application, and/or where the participant would otherwise defeat much of the effect of the CSS by tensing the muscles in the affected area prior to the application. Electrodes were rotated to different skin locations at the end of each hour and after a skin-shock was applied.

In certain cases, when equipment failure or other factors prevented the administration of the skin-shock, a verbal reprimand was substituted.

During the treatment phase, each time the student displayed an aggressive behavior, the staff member who administered the GED recorded the apparently-triggering stimulus as well as other setting information on the participant's daily recording sheet. This information was used by the clinician in his or her ongoing *in vivo* functional analysis of the aggressive behavior.

Although a detailed analysis of the gradual removal (fading) of the GED device was beyond the scope of this study, fading was accomplished with many of the participants. As their behaviors improved, the requirement that the GED device be worn was gradually diminished. If participants had been wearing more than one GED, the number was gradually reduced to just one. At that point, and in cases where the participant had always been using only one device, the number of hours each day during which the device was worn was gradually reduced to zero.

All 60 participants were included in the Treatment phase. A total of 52 were started on CSS using the GED-1, and 8 were started using the GED-4. The decision as to which to start with was made by the clinician, and depended on factors such as the seriousness and severity of the problem behavior, the participant's previous history, and the need to maximize the likelihood of rapid and effective treatment.

In two cases, the GED-1 was employed first and the participant was later switched to the GED-4 either because the GED-1 was judged to be insufficiently effective in treating the aggression, or because it

was insufficiently effective in treating one or more of the other behavior categories that were being treated concurrently.

RESULTS

Chart display

Individual charts showing weekly totals for the participants' aggressive behaviors are presented in Figure 1. There is one chart for each participant and each participant is identified as Participant 1, Participant 2, etc. The charts are multiply/divide charts in which a relative change (e.g., a doubling, tripling, or halving) occupies a constant up-down distance anywhere on the chart. Each vertical line represents 1 week and heavy vertical lines represent every 5th week. A dashed vertical phase line indicates the week during which the participant's treatment program was supplemented with the GED-1 or GED-4. These charts are very similar, but not identical[1], to the weekly version of the Standard Celeration Chart (Pennypacker, Guiterrez and Lindsley, 2003) that is employed in Precision Teaching (Lindsley, 1990).

The data point for each "CSS introduction-week"—i.e., the week within which the GED procedure was introduced—has been omitted because the total for that week, which was based on one or more days from both the baseline and treatment phases, belonged in neither phase. The data for those weeks are provided in the Appendix. Similarly, in the two cases (Participants 29 and 31) in which a participant was changed from the GED-1 to the GED-4 during the treatment phase, the data point for the week during which the change was made has been omitted because the total for that week, which was based on one or more GED-1 days as well as one or more GED-4 days, belonged in neither condition. The data for those weeks also, are provided in the Appendix.

The charts are arranged vertically in a single column according to the date on which the GED was added to the participant's program. As a result, the charts are displayed in what amounts to a multiple-baseline-across-participants display with the intervention line (that shows the introduction of the GED) jogging to the right after each chart to show the passage of time before the next participant started on the GED.

Casual inspection of these charts shows that the supplemental use of the GED was effective in decelerating aggression in almost every single case. This is particularly evident when one takes into account the fact that on these charts (when displayed at 100% size on a computer screen) a vertical distance of approximately 6.35 mm (1/4 in) upwards or downwards, represents a doubling or halving, respectively, of the frequency.

For some participants gradual removal or fading of the GED occurred. As of December 1, 2007, 23 of the 60 participants (38%) had been able to dispense totally with wearing any GED device. Eight of these 23 had left JRC after being completely faded from the GED and moved on to less restrictive settings such as other residential schools, day programs, regular school settings, or their own home. Fifteen others were still enrolled at JRC and had various forms of partial independence in the school and in their residence. Three of the 15 had paid in-school jobs. Because many of the participants were still undergoing active treatment at the time of this report, further removals and fading that occurred after the end of the 3-year period covered in this report are not included.

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[1] On the charts of Figure 1, a data series that doubles *every 5 weeks* produces a slope of 34 degrees. On the weekly version of the Standard Celeration Charts, a doubling *every month* produces the same slope.

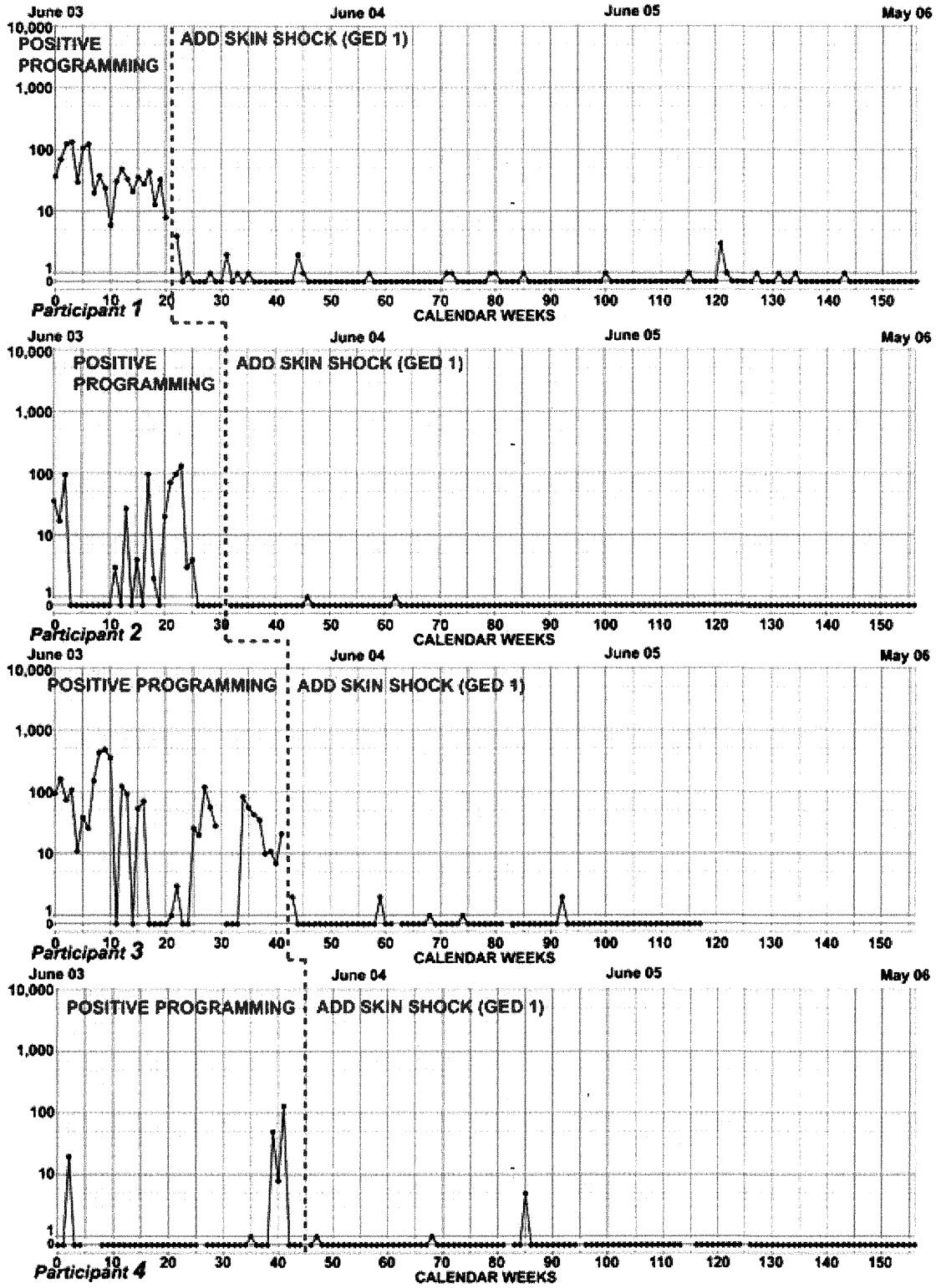

June 03
June 04
June 05
May 06
POSITIVE PROGRAMMING
ADD SKIN SHOCK (GED 1)
10,000
1,000
100
10
1
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150
CALENDAR WEEKS
Participant 1
Participant 2
Participant 3
Participant 4

Figure 1. The weekly frequency of aggressive behaviors for each participant between June 1st, 2003 and May 30, 2006.

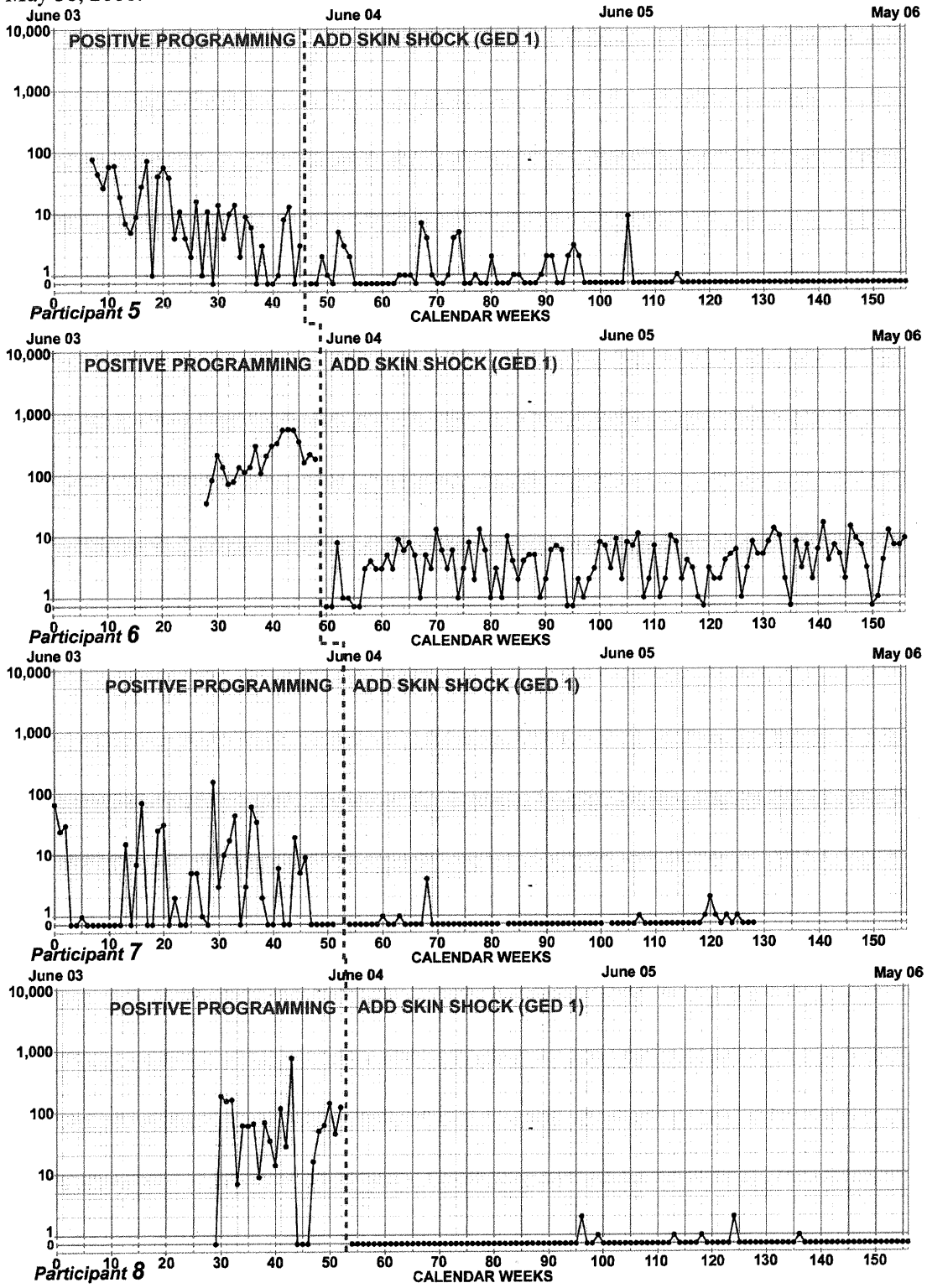


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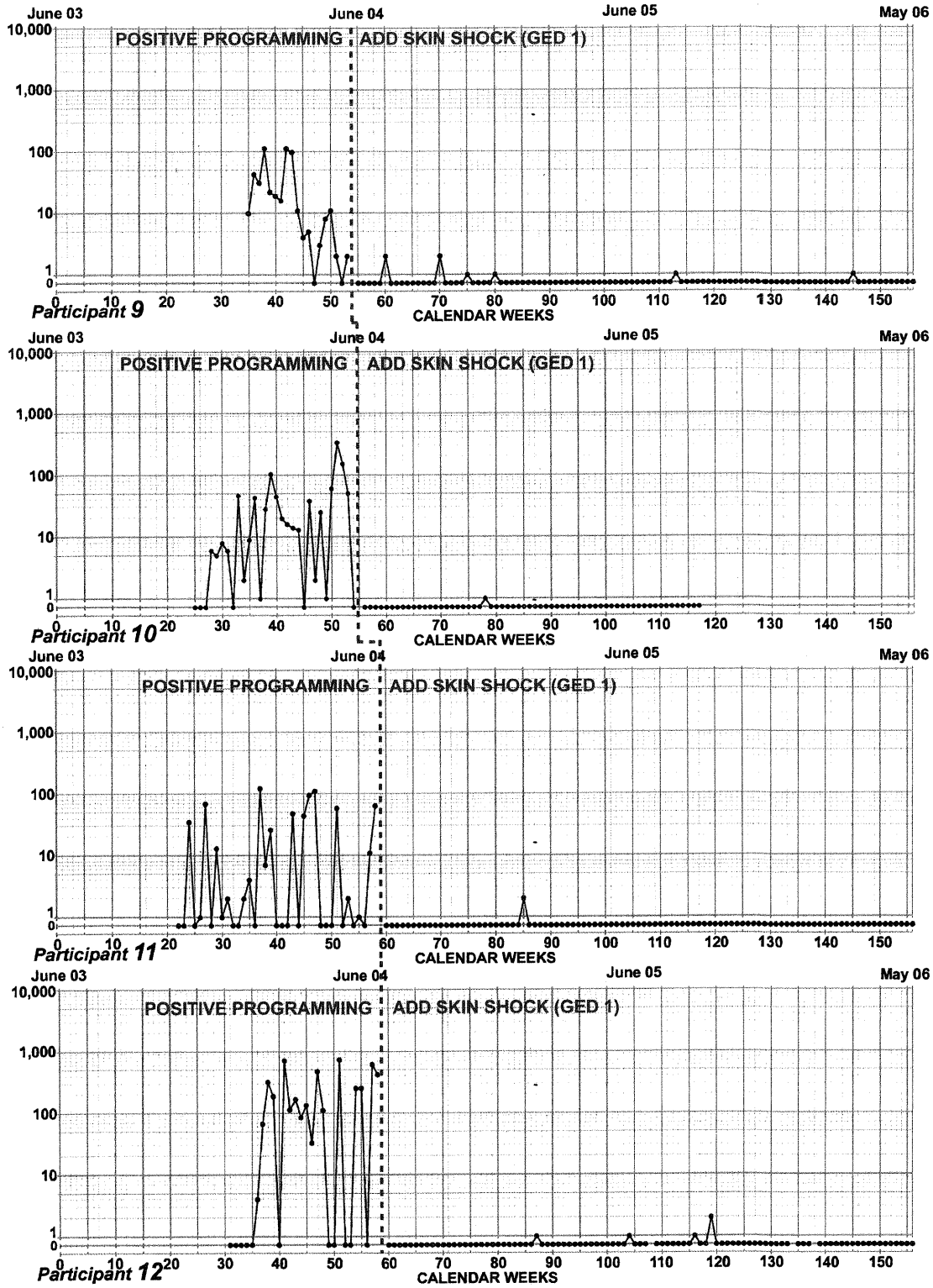
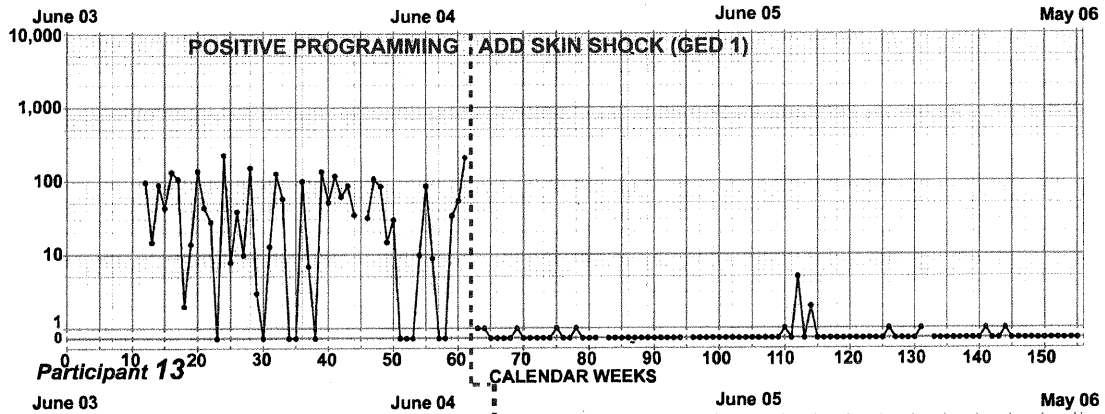
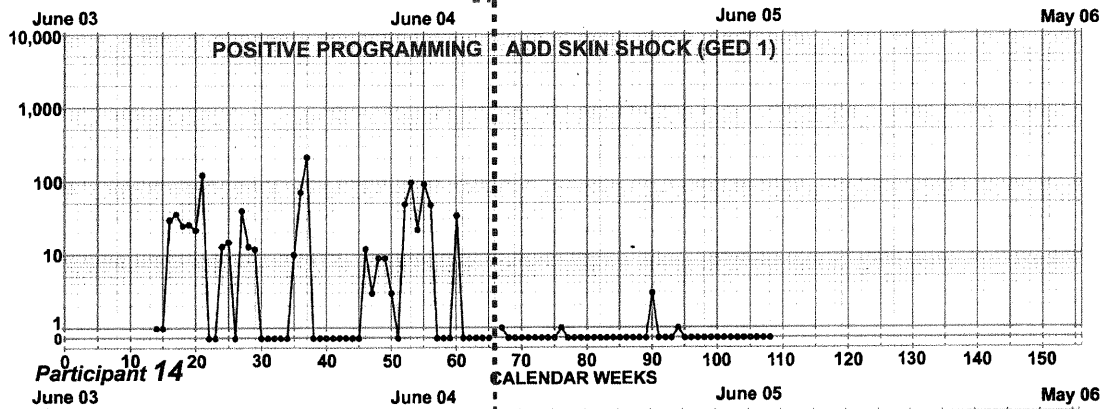


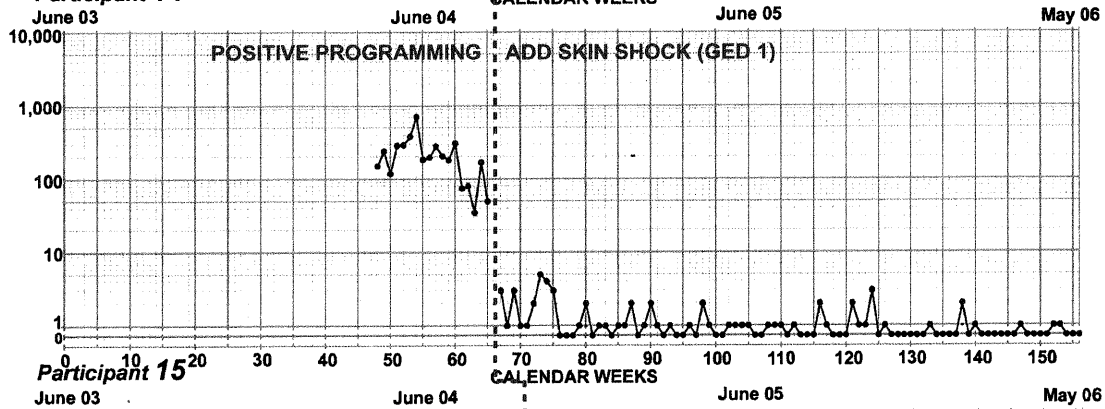
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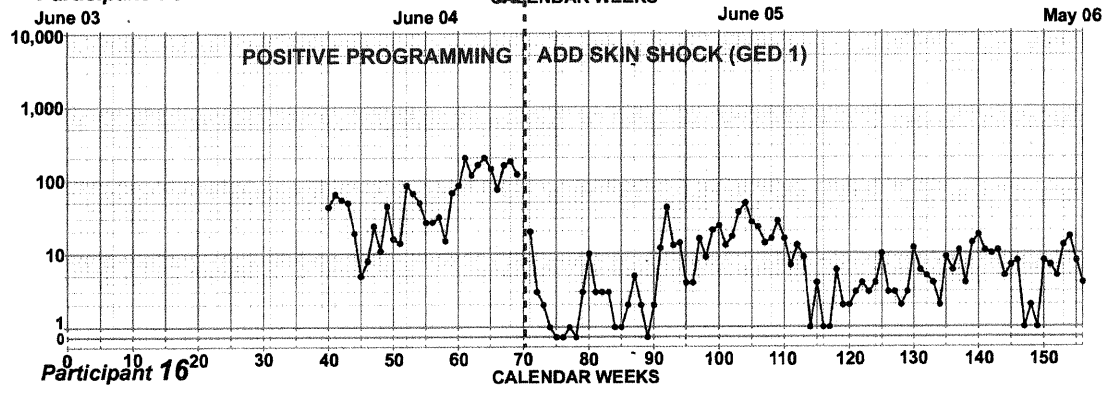
Participant 13



Participant 14



Participant 15



Participant 16

Figure 1(continued).

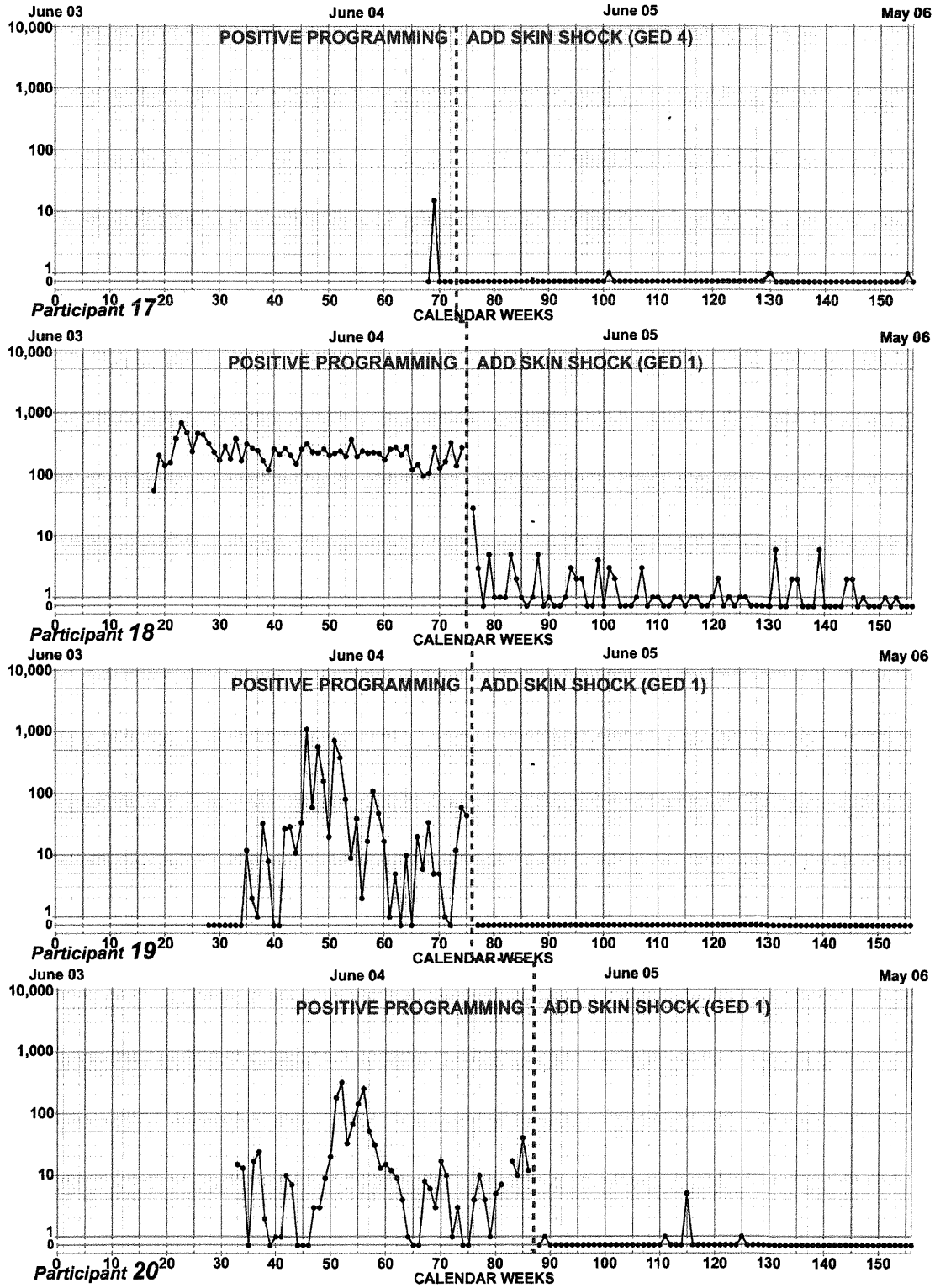


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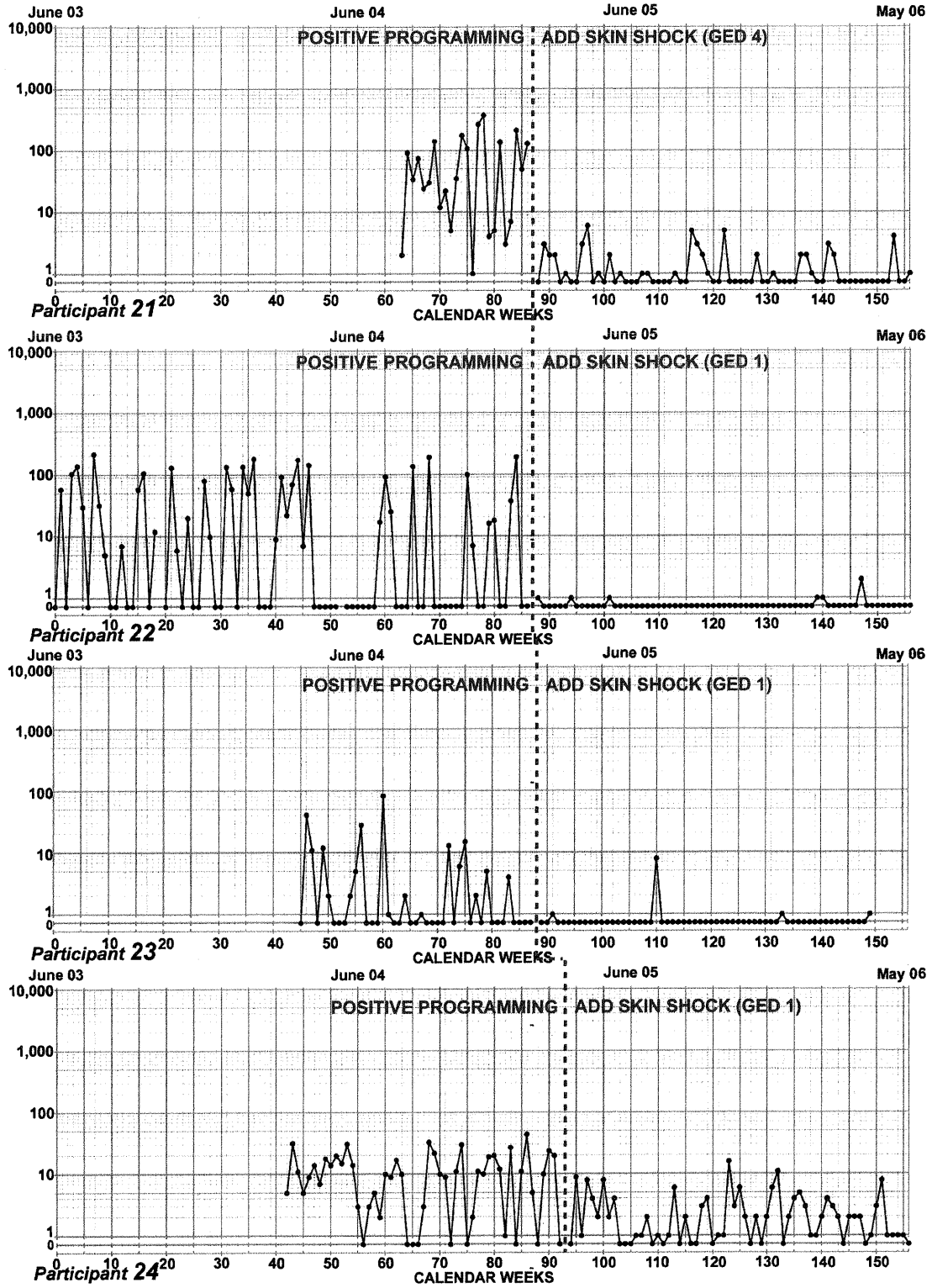


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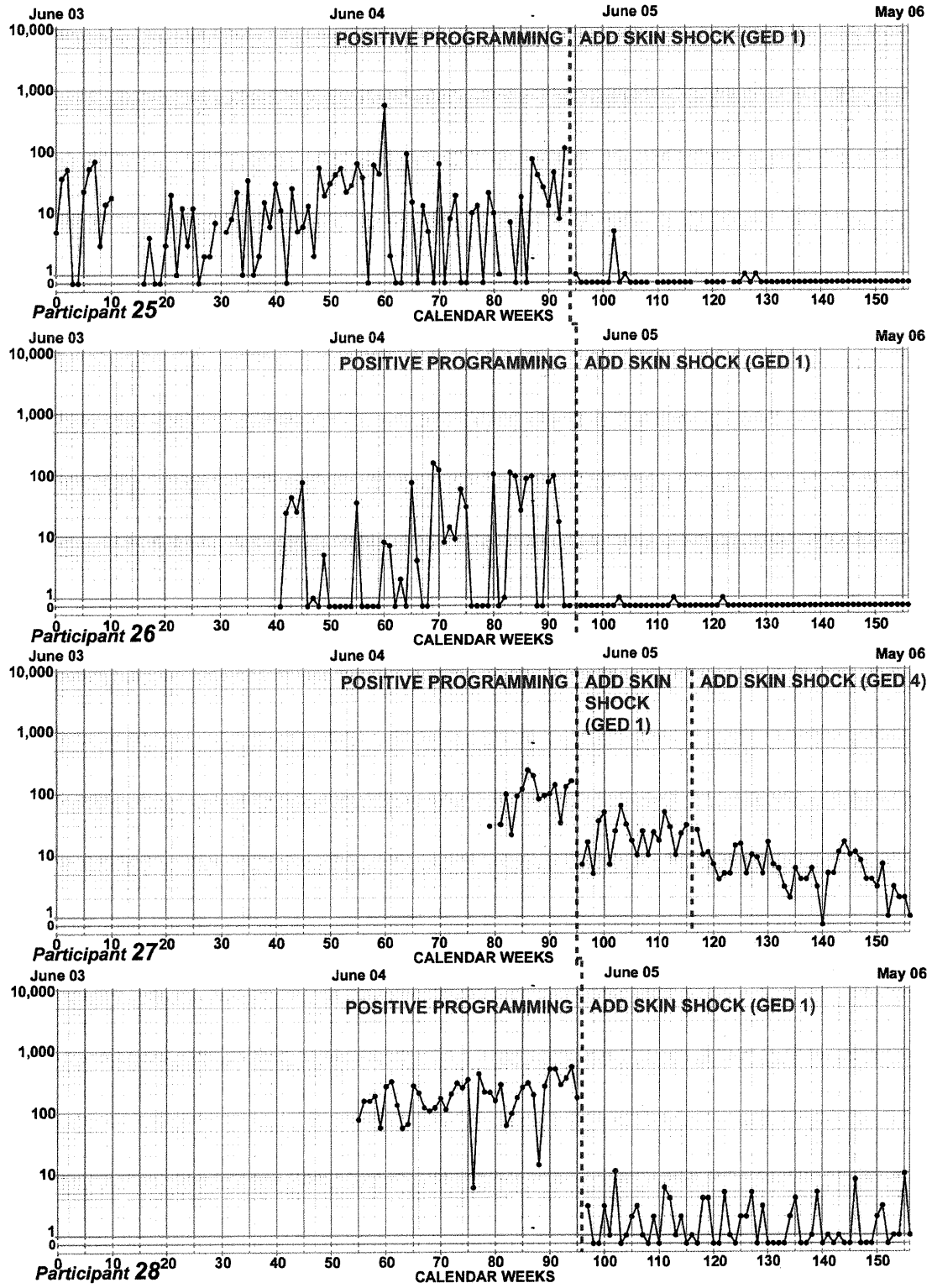


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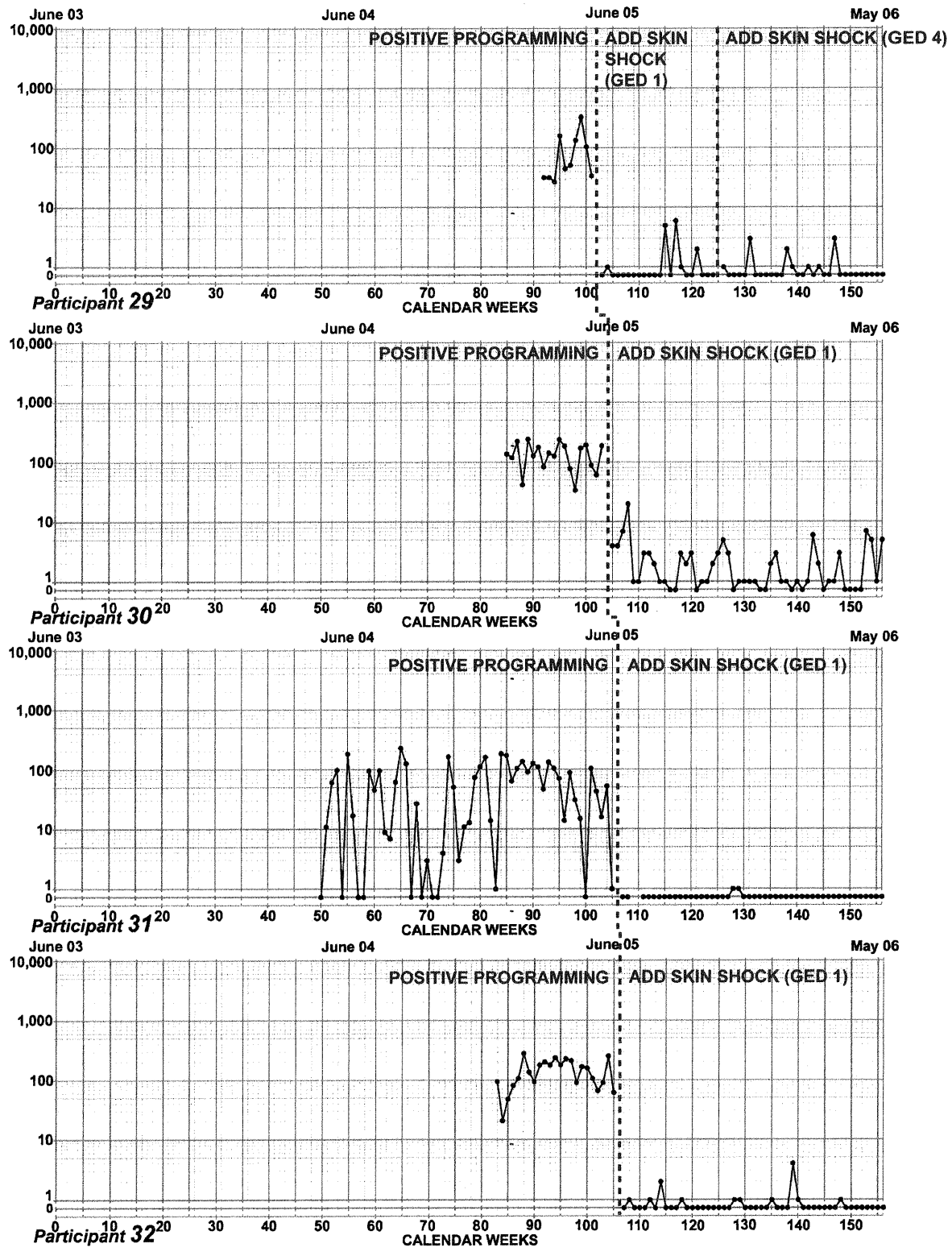
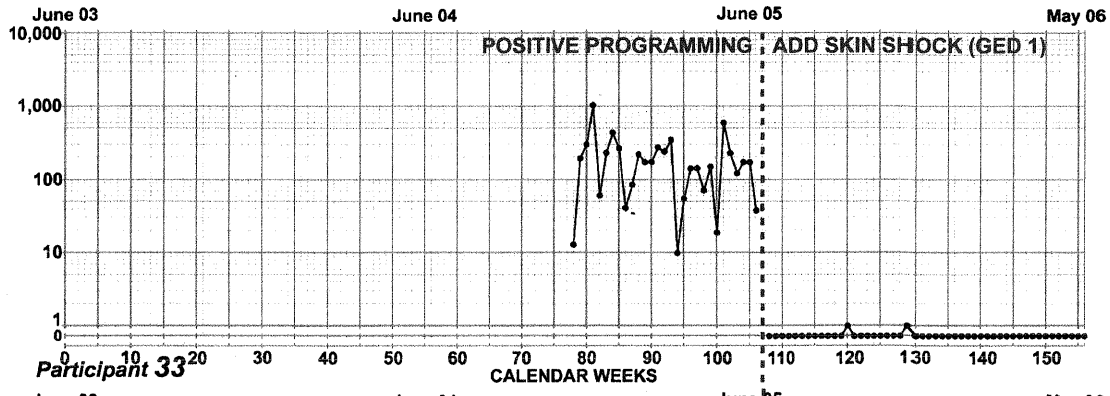
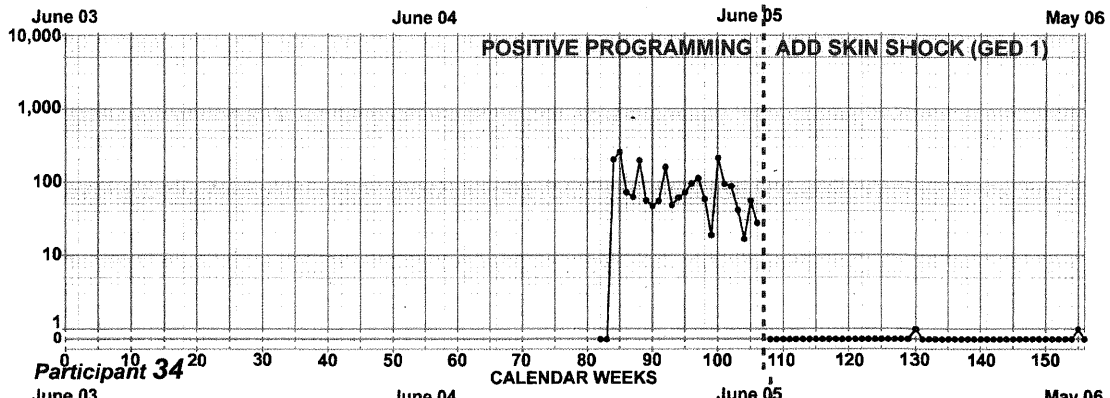
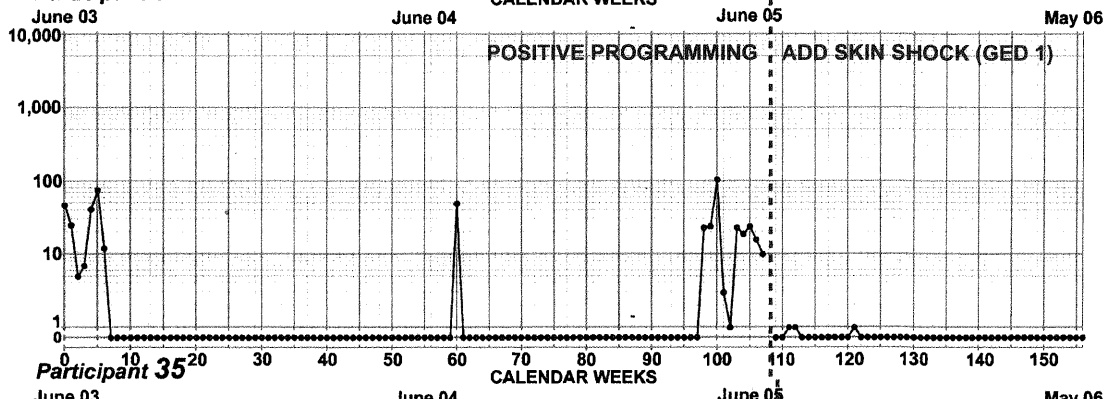


Figure 1(continued).


June 03
June 04
June 05
May 06
POSITIVE PROGRAMMING
ADD SKIN SHOCK (GED 1)
10,000
1,000
100
10
1
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150
CALENDAR WEEKS
Participant 33


June 03
June 04
June 05
May 06
POSITIVE PROGRAMMING
ADD SKIN SHOCK (GED 1)
10,000
1,000
100
10
1
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150
CALENDAR WEEKS
Participant 34


June 03
June 04
June 05
May 06
POSITIVE PROGRAMMING
ADD SKIN SHOCK (GED 1)
10,000
1,000
100
10
1
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150
CALENDAR WEEKS
Participant 35

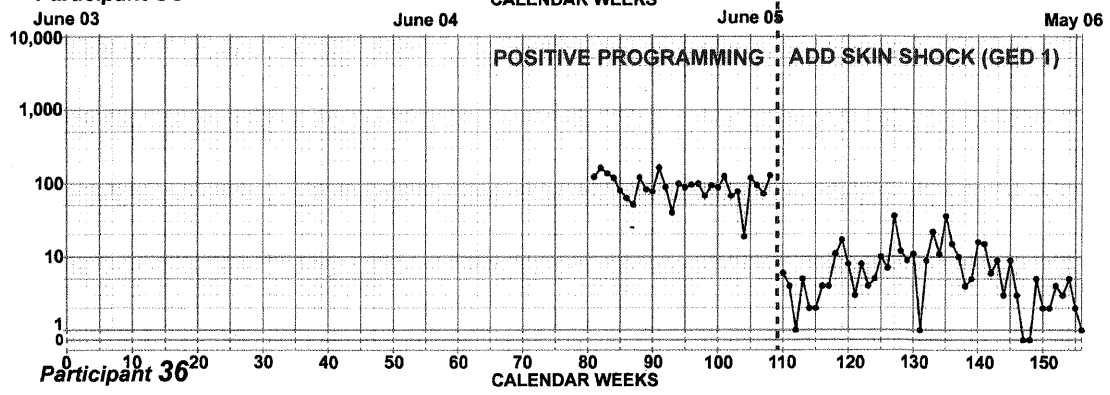

June 03
June 04
June 05
May 06
POSITIVE PROGRAMMING
ADD SKIN SHOCK (GED 1)
10,000
1,000
100
10
1
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150
CALENDAR WEEKS
Participant 36

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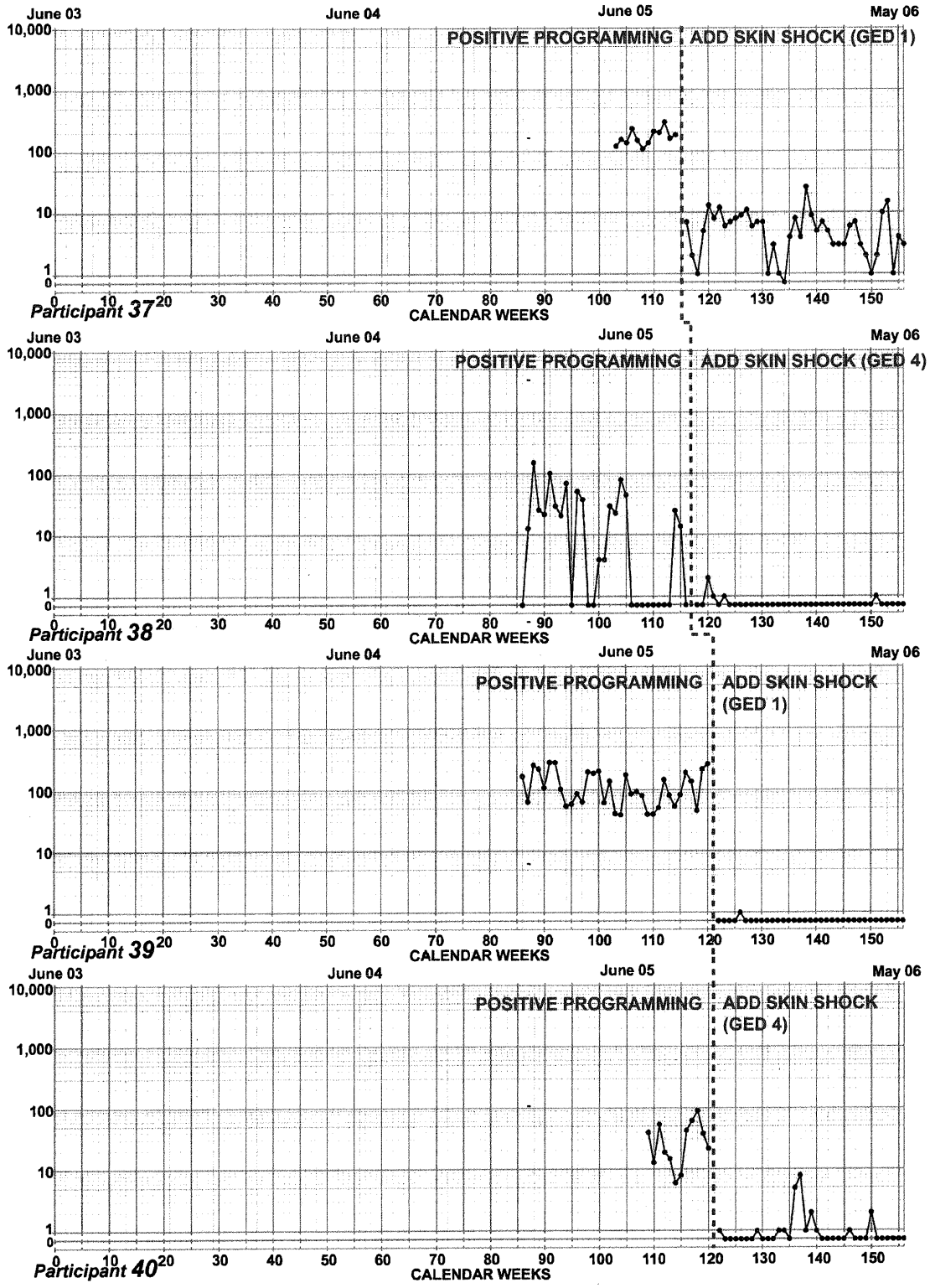


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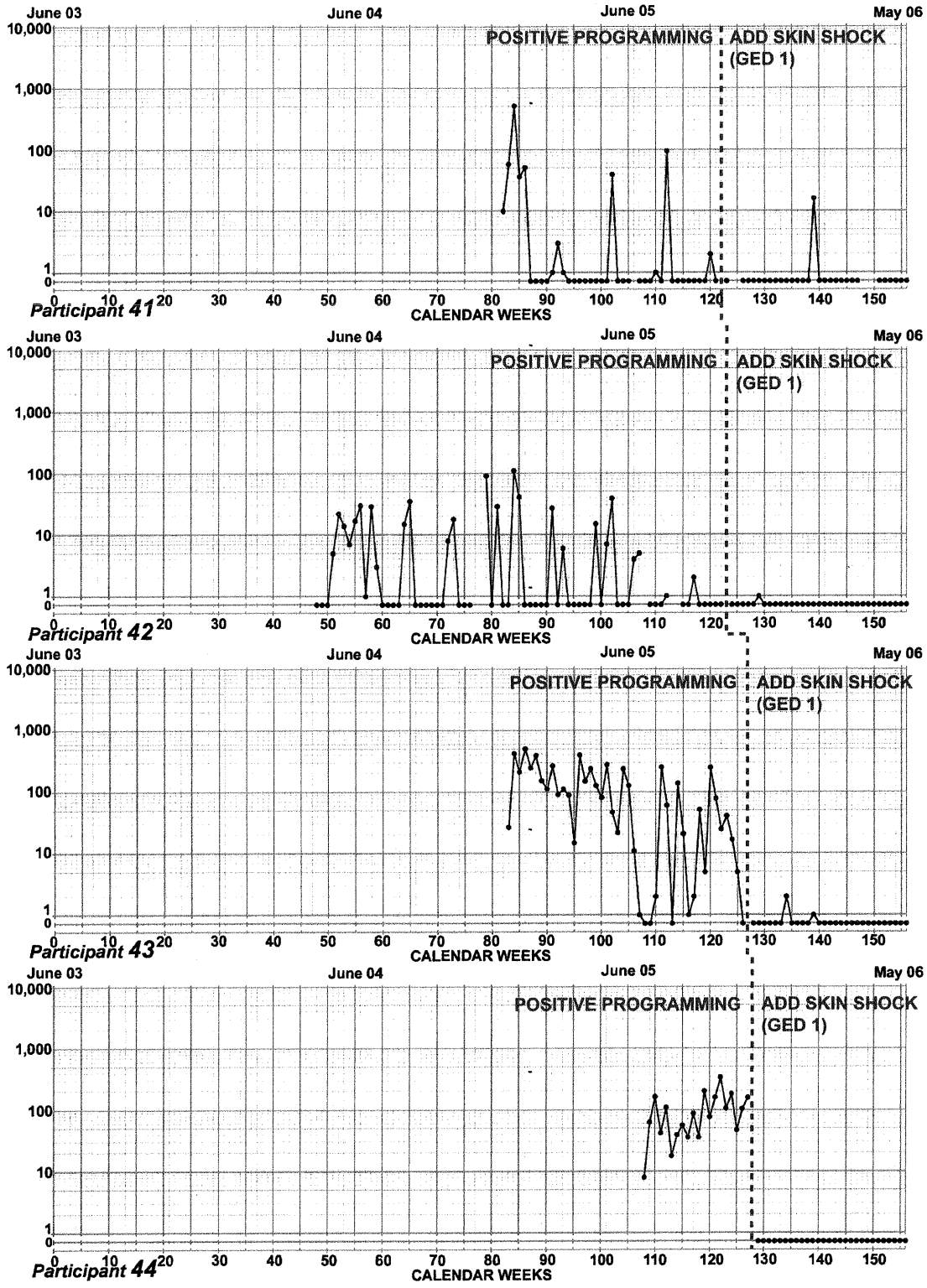


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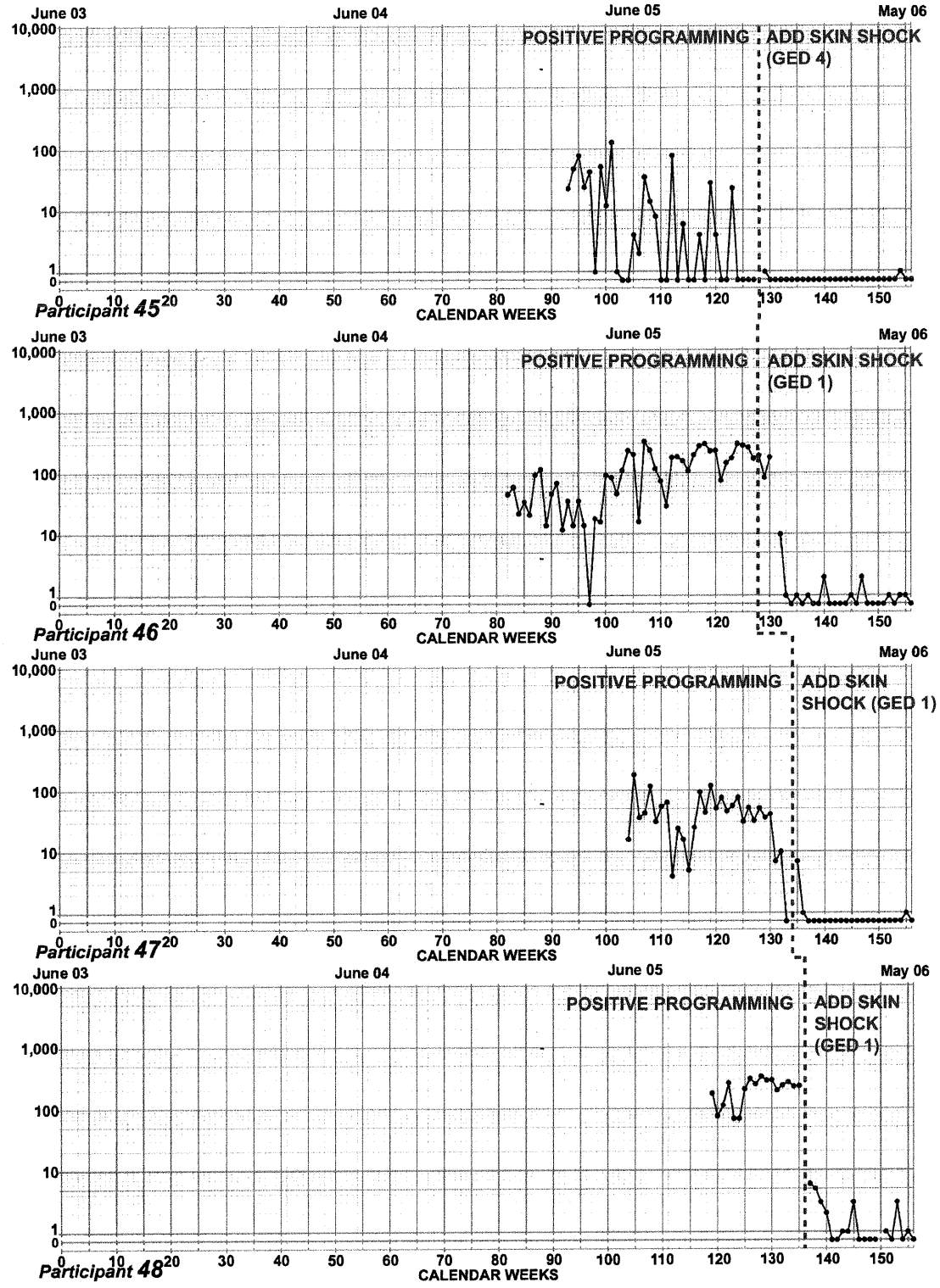


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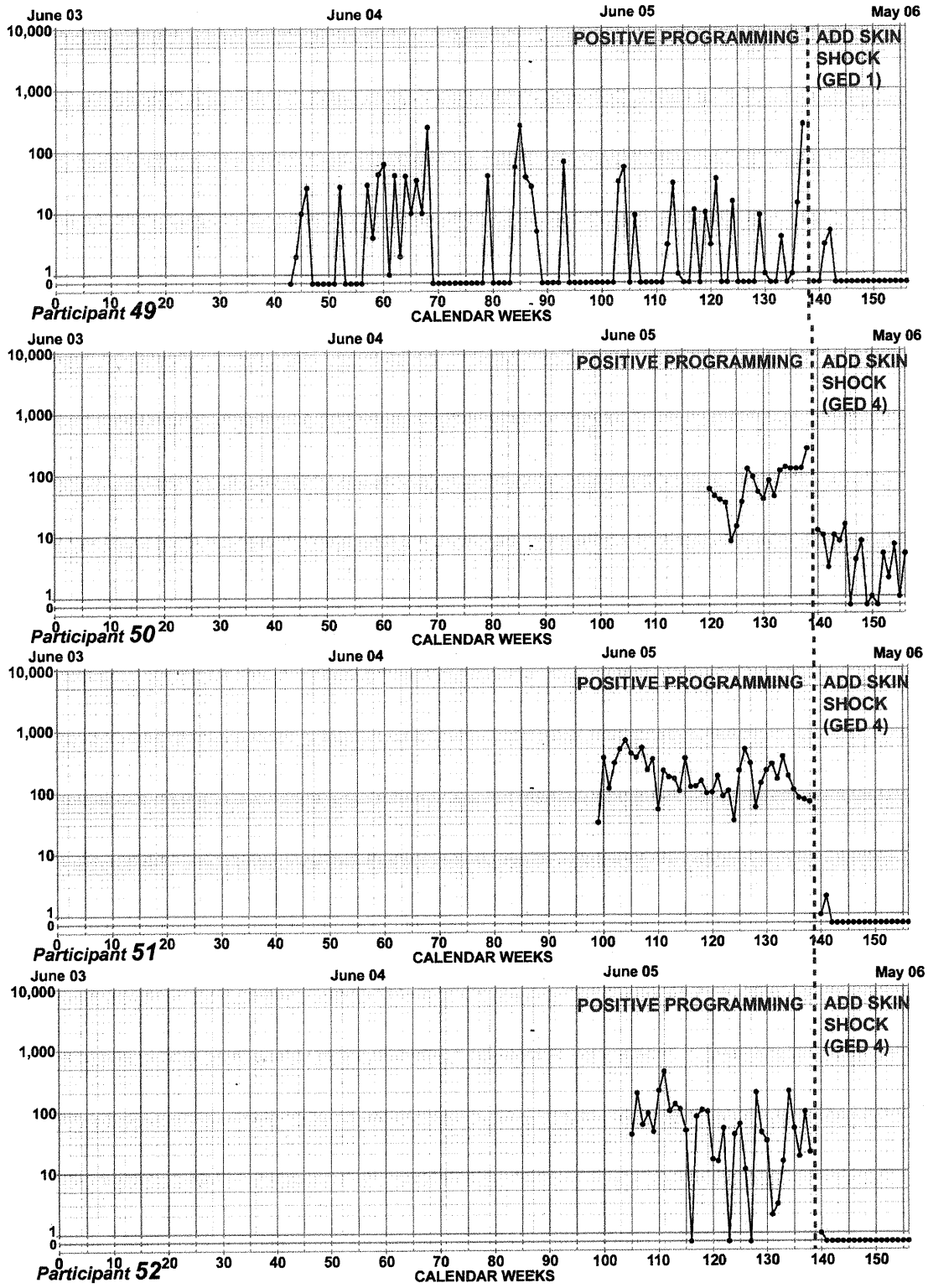


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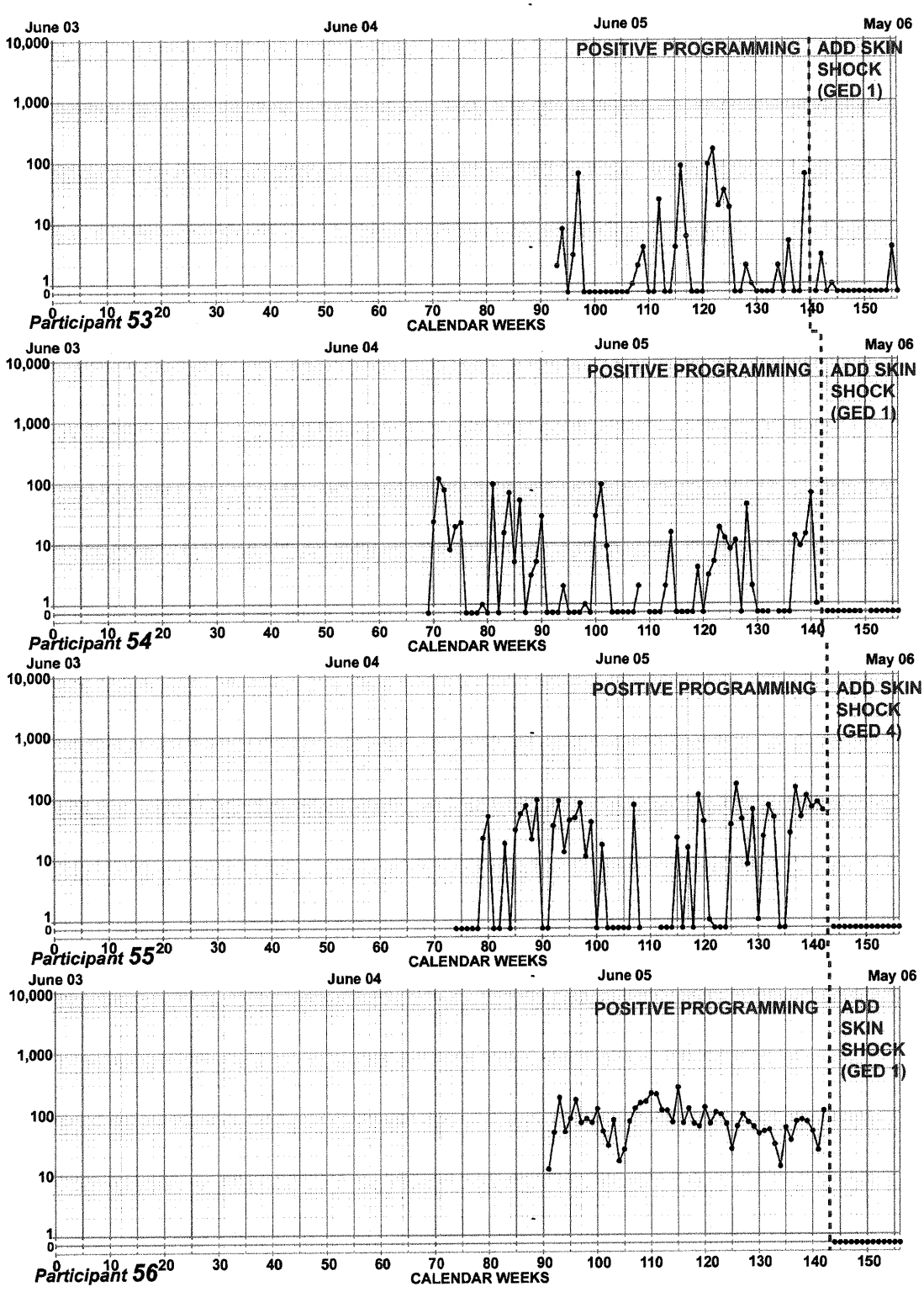


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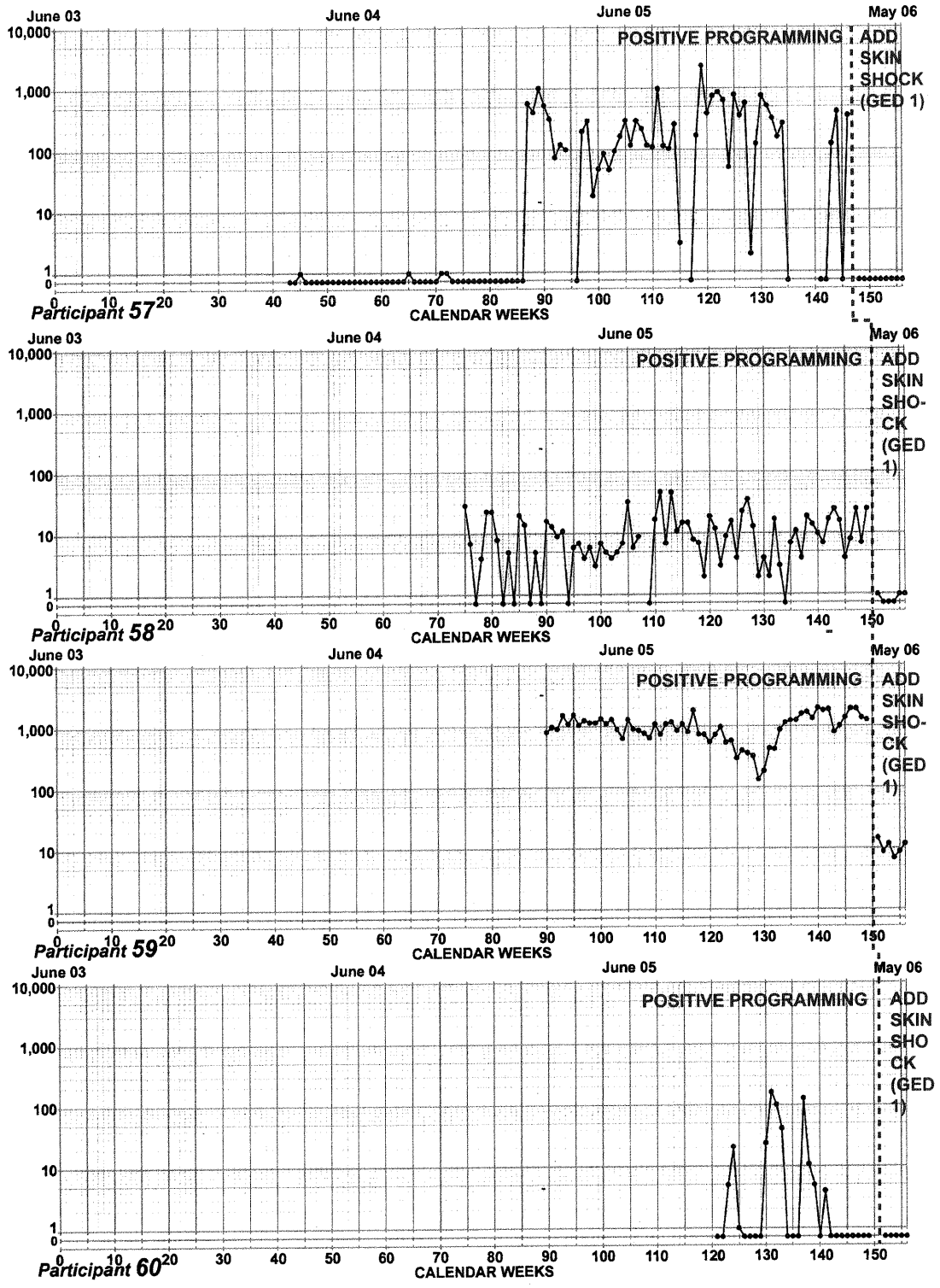


Figure 1(continued).

Trends during baseline

Table 2 summarizes the trends seen during the baseline (positive programming) phase. In 40 participants (68% of the 59 cases where there was sufficient information to characterize the trend), the frequency was either increasing (accelerating) or flat when CSS was introduced. In the remaining 19 cases, even though the behavior was decreasing in frequency (decelerating), CSS was introduced because the behavior was too dangerous to be allowed to occur at the frequency it was showing.

Table 2

Trends of aggressive behavior during baseline

Description	Total	Participant numbers
Acceleration	23	2, 6, 8, 10, 11, 16, 19, 25, 26-29, 33, 37, 40, 44, 46, 48, 50, 55, 57-59
Flat	17	4, 7, 13, 14, 18, 20, 22-24, 34-36, 39, 42, 47, 49, 54
Deceleration	19	1, 3, 5, 9, 12, 15, 21, 30-32, 38, 41, 43, 45, 51-53, 56, 60
Insufficient Information	1	17

Decelerative effect of CSS on aggressive behaviors

To analyze CSS's decelerative effect, we examined: (1) the initial change in frequency associated with the introduction of CSS; (2) the overall chart patterns found during the treatment phase; (3) the overall decelerative effect seen when all baseline data is compared with all treatment data; and (4) the changes in trends from baseline to treatment.

Initial effect on frequency

In almost every chart in Figure 1, the GED is shown to produce two separable effects. It causes an immediate decrease in frequency (jump down) right after it is introduced, and this is followed by some other trend over the succeeding weeks.[2] We chose to measure these immediate jump downs by plotting the trend (celeration) lines for both the baseline and treatment data, and measuring the vertical distance between the end of the baseline celeration line and the beginning of the treatment celeration line. If there was more than one trend during baseline or treatment, we used the last trend in the baseline data and the initial trend in the treatment data.

Figure 2 is an example of how this was done. The size of the jump down at the time of CSS introduction is the same up/down distance as the distance between 1 and 85 on the vertical scale of the multiply/divide chart in Figure 2. Therefore the jump would be characterized as a "÷ 85" (read "divide 85") jump down which means that the frequency divided by a factor of 85. Table 3 shows the jump down that occurred immediately after CSS introduction for each participant. It shows that median jump down was ÷27, meaning that the weekly frequency made an immediate decrease by a factor of 27.

[2]This observation was first brought to our attention by the late O.R. Lindsley, who also developed the precision teaching technology on which we have based much of our charting scheme and data analysis.

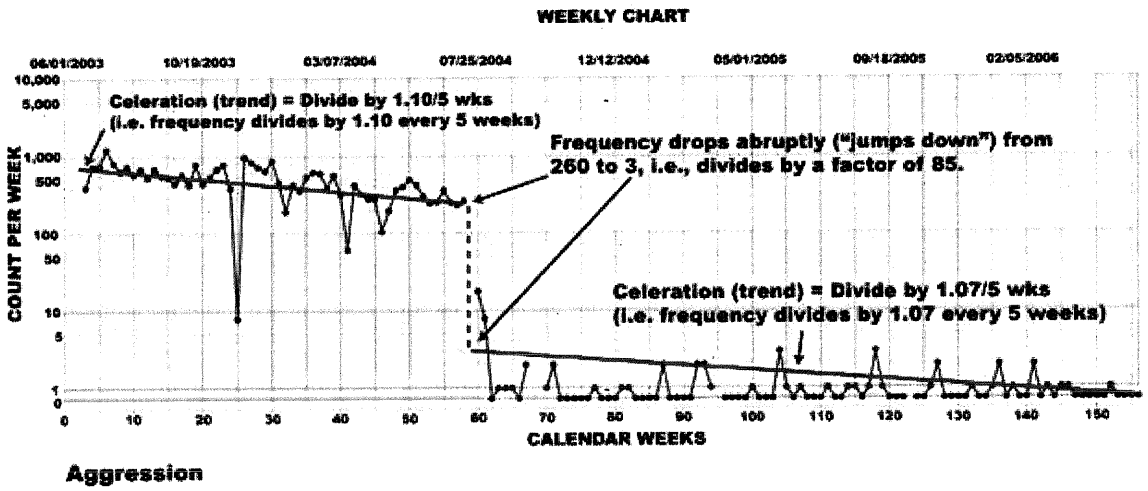


Figure 2. Sample weekly chart showing calculation of frequency jump down

Overall chart patterns during treatment phase

We classified each of the charts in Figure 1 into five categories, according to the extent of the initial jump down (i.e., whether frequency dropped to zero or not) and the trend of the data after that point. The result of this classification is shown in Table 4 which also shows the percent of cases that fall into each category.

In 48 cases (80% of the participants), aggressive behaviors were reduced immediately to a zero or near-zero level and remained at that level for whatever time remained in the 3-year period. In 5 cases (8.3%) the frequency jumped down and then showed a deceleration, but had not yet reached zero within the remainder of the 3-year period. Therefore, in 53 cases (88.3%), the behavior either jumped down to zero or near-zero immediately, or jumped down and then decelerated toward zero. In the remaining 7 cases (categories 3-5), although several different trends were seen after the initial jump down, the level of aggression during the treatment phase was substantially lower than during baseline (see next section, below) and reflected clinically meaningful improvement.

Overall decrease in frequency from baseline to treatment

For each participant, we calculated the overall mean weekly frequency of aggressive behaviors across the entire baseline phase, the overall mean weekly frequency across the entire treatment phase, and the respective standard deviations. We then calculated improvement for each participant in terms of both the percent and the factor by which the baseline mean weekly frequency had been reduced. These data are shown in Table 5.

The results are further summarized in Tables 6 and 7, and Figure 3. In Table 6, total frequency, number of weeks, standard deviation, mean per week, median per week, and range are presented for the baseline and treatment phases. In Table 7, the number of participants who achieved various percent reductions from baseline are presented. Percent reduction was calculated using the entire baseline and entire treatment means. Table 7 shows that for 30 (50%) of the participants, aggressive behaviors were reduced by 100%, and that for 57 (95%), aggressive behaviors were reduced by 92% or more.

Table 3

Frequency jump downs occurring immediately after CSS introduction (organized by magnitude)

Frequency jump down Immediately after CSS Introduction	Participant Number	Frequency jump down Immediately after CSS Introduction (continued)	Participant Number (continued)
÷800	57	÷26	8
÷500	12	÷21	17
÷150	32	÷20	4
÷120	46	÷20	34
÷110	44	÷19	2
÷110	51	÷18	21
÷100	28	÷16	19
÷100	33	÷16	38
÷90	59	÷15	35
÷85	18	÷15	36
÷80	6	÷15	50
÷80	48	÷15	53
÷60	56	÷12	39
÷56	15	÷11	3
÷52	29	÷11	25
÷50	22	÷10	49
÷49	26	÷9	1
÷45	31	÷9	58
÷44	10	÷7	20
÷42	13	÷7	42
÷40	11	÷6	7
÷40	30	÷6	45
÷40	55	÷5	54
÷36	37	÷4	24
÷30	14	÷3	41
÷30	40	÷3	43
÷30	47	÷1.6	23
÷30	60	÷1.5	5
÷29	52	÷1.5	9
÷28	16	÷1.5	27

Median = ÷27

Table 4

Summary of frequency patterns during treatment phase

	Pattern Shown by Frequency During Treatment Phase	Number of Cases	Percent of Cases	Charts
1	Jump down to zero or near-zero level; then maintenance at that level	48	80	1-4, 7-15, 17-23, 25, 26, 29, 31-35, 38-47, 49, 51-58, 60[a]
2	Jump down to non-zero level; then a deceleration	5	8.3	5, 37, 48, 50, 59
3	Jump down to non-zero level; then maintenance at that level.	3	5	24, 28, 30
4	Jumps down to non-zero level; then acceleration	1	1.7	6
5	Jumps down to non-zero level; then alternating accelerations and deceleration(s)	3	5	27, 36, 16
	Totals	60	100	

[a] Although this classification of this data series for participant 60 as a flat celeration at a zero frequency is based on only five data points, examination of the next 6 weeks of data (which are outside of the 3-year period covered in these graphs) showed that the behavior maintained at 0 during those weeks, confirming the present classification.

Table 5

Comparison of all Baseline Weeks with All Treatment Weeks

Participants	Mean Weekly Frequency During Entire Baseline Period	SD During Entire Baseline Period	Mean Weekly Frequency During Entire Treatment Period	SD During Entire Treatment Period	Percent Reduction from Baseline (means)	Reduction from Baseline (Divide by Factor)
1	48.14	39.64	0.21	0.58	100	229
2	17.03	37.41	0.02	0.13	100	852
3	68.61	111.47	0.11	0.42	100	69
4	5.1	20.72	0.07	0.49	99	73
5	17.56	22.07	0.59	1.45	97	30
6	222.77	155.7	4.67	3.61	98	48
7	12.4	26.1	0.18	0.58	99	69
8	90.79	155.13	0.09	0.35	100	1009
9	26.79	37.59	0.08	0.34	100	335
10	34.4	66.22	0.02	0.13	100	1720
11	19.32	33.72	0.02	0.2	100	966
12	167.61	227.11	0.05	0.27	100	3352
13	53.43	57.88	0.21	0.67	100	254
14	19.83	38.83	0.14	0.52	99	142

Table 5 (Continued).

Comparison of all Baseline Weeks with All Treatment Weeks

Participants	Mean Weekly Frequency During Entire Baseline Period	SD During Entire Baseline Period	Mean Weekly Frequency During Entire Treatment Period	SD During Entire Treatment Period	Percent Reduction from Baseline (means)	Reduction from Baseline (Divide by Factor)
15	220.94	156.59	0.77	1.01	100	287
16	73.1	61.63	8.74	9.36	88	8
17	3	6.71	0.04	0.19	99	75
18	239.51	106.68	1.36	3.34	99	176
19	77.08	205.5	0	0	100	77
20	26.68	60.87	0.1	0.62	100	267
21	80.63	96.71	0.84	1.39	99	96
22	33.83	56.33	0.1	0.35	100	338
23	5.42	14.53	0.18	1.04	97	30
24	11.53	10.45	2.51	3.05	78	5
25	24.59	59.68	0.14	0.66	99	176
26	25.72	39.85	0.05	0.22	100	514
27	102	64.96	12.15	12.73	88	8
28	204.27	121.44	1.78	2.45	99	115
29	94.7	94.97	0.76	1.22	99	125
30	140.58	64.59	2.17	3.12	98	65
31	60.7	61.11	0.04	0.2	100	1518
32	136.42	71.57	0.34	0.87	100	401
33	208.14	207.03	0.04	0.2	100	5204
34	85.36	69.81	0.04	0.2	100	2134
35	4.7	15.01	0.06	0.24	99	78
36	94.96	33.65	7.77	7.75	92	12
37	174.42	53.23	5.98	4.8	97	29
38	24.26	35.59	0.13	0.41	99	187
39	125.46	76.98	0.03	0.17	100	4182
40	34.25	25.58	0.69	1.6	98	47
41	20.87	83	0.55	2.74	97	38
42	8.31	18.69	0.03	0.17	100	277
43	122.75	133.78	0.1	0.41	100	1228
44	101.95	80.75	0	0	100	102
45	17.6	29.06	0.07	0.26	100	242
46	121.37	95.28	0.84	2.01	99	144
47	47.93	39.35	0.41	1.5	99	117
48	213.06	85.11	1.37	1.81	99	156
49	16.73	47.02	0.44	1.34	97	38
50	79.89	58.98	5.35	4.61	93	15
51	215.9	155.64	0.18	0.53	100	1204
52	76.56	87.73	0.06	0.24	100	1268
53	12.81	31.28	0.5	1.21	96	26
54	12.47	24.84	0	0	100	13

Table 5 (Continued).

Comparison of all Baseline Weeks with All Treatment Weeks

Participants	Mean Weekly Frequency During Entire Baseline Period	SD During Entire Baseline Period	Mean Weekly Frequency During Entire Treatment Period	SD During Entire Treatment Period	Percent Reduction from Baseline (means)	Reduction from Baseline (Divide by Factor)
55	30.33	38.12	0	0	100	30
56	81.19	49.95	0	0	100	81
57	172.94	324.67	0	0	100	173
58	11.19	10.29	0.5	0.55	96	22
59	1027.51	467.22	10.67	2.88	99	96
60	16.87	40.89	0	0	100	17
	Median = 57.07	**Median = 59.33**	**Median = 0.14**	**Median = 0.54**	**Median = 99.5**	**Median = 121**

Note: When the treatment weekly mean was equal to zero, the number 1 was substituted in order to calculate the factor by which the treatment mean was reduced. This was the case for participants 19, 44, 54, 55, 56, 57, and 60.

Table 6

Descriptive Statistics of all Participants during Baseline and treatment

	Baseline	Treatment
Total Frequency of Aggressive Behaviors	220,873	3,764
Number of Participant-Weeks	2,489	3,196
Mean per Week	88.74	1.18
Standard Deviation	203.67	3.79
Median per Week	17	0
Range	0 - 2367	0 - 62

Table 7

Percent of participants achieving certain percentage reductions

Percent Reduction	Number of Participants	Cumulative Number at or above this Percent Reduction	Cumulative Percent at or above this Percent Reduction
100	30	30	50.0
99	15	45	75.0
98	3	48	80.0
97	5	53	88.3

Table 7 (Continued).

Percent of participants achieving certain percentage reductions

Percent Reduction	Number of Participants	Cumulative Number at or above this Percent Reduction	Cumulative Percent at or above this Percent Reduction
96	2	55	91.7
95			
94			
93	1	56	93.3
92	1	57	95.0
91			
90			
88	2	59	98.3
78	1	60	100.0

The frequency distributions for the mean weekly frequency of baseline and treatment are presented in Figure 3. The baseline portion shows that of the 11 intervals, at least one student had a mean weekly frequency that fell within 10 of the intervals. By contrast, the treatment portion shows that all 60 students had a mean weekly frequency that fell within the first interval (a mean weekly frequency of 0-25).

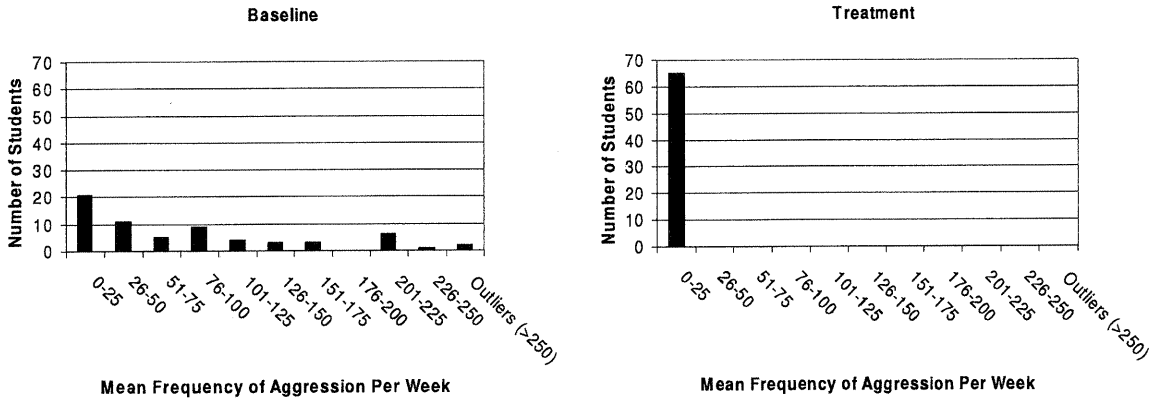


Figure 3. Frequency distribution of the weekly means.

Results of paired sample t-test and effect size

Using a paired sample *t*-test, we compared the means of aggression during baseline with the means of aggression during treatment. The difference between the means was found to be significant, $t(59)=5.01$, $p < .001$. In order to assess the magnitude of the effect, we utilized Cohen's *d* with the original standard deviation values. The effect was found to be large, $d = .91$.

Comparison of percentage reduction found in this study with those found in treatment outcome reviews

We compared the percentage reduction that we found in the present study with those reported in two treatment outcome reviews: (1) one by Cataldo (1991), who evaluated published studies (1965-1989) in which punishment was used to treat problem behaviors; and (2) one by Carr et al. (1999) who evaluated published studies (1995-1996) in which Positive Behavior Support procedures were use used to treat problem behaviors. The results, including the methods for calculating percentage reduction are shown in Table 8.

Table 8

Percentage Reductions Reported in Present Study and Two Other Treatment Outcome Reviews

Report	Type of Study	No. of Participants/Outcomes[a] Evaluated re Treatment of Aggression	Treatment Methods	Method of Calculating Percentage Reduction	Percent of Participants/Outcomes Achieving a Reduction of 90% or More
Cataldo (1991)	Treatment outcome review of 137 punishment studies, 1965-1989	4 participants	CSS employed with one or more other interventions.	Mean of all baseline data compared with mean of last 3 treatment data	60.0%
Carr et al. (1999)	Treatment outcome review of 109 Positive Behavior Support studies, 1985-1996	90 outcomes	Positive behavioral procedures only	Mean of last 3 baseline data compared with mean of last 3 treatment data	55.5%
Israel et al. (present study)	Treatment of 60 participants using multiple baseline design, 2003-6	60 participants	Positive behavioral procedures plus CSS	Mean of last 3[b] baseline weeks compared with mean of last 3 treatment weeks	100%[c]

[a] Carr (1999) evaluated "outcomes," not participants. If a single subject study used time out, then ignoring and then skin shock in three successive phases, this was counted as 3 outcomes. The Carr report does not provide information as to how many participants were involved in the 90 outcomes in which Positive Behavior Support procedures were employed to treat aggression. [b]For participants 2, 4, 7, 14, 17, 23, 42, 45, and 60 the mean of the last 3 baseline weeks was equal to zero. For those cases, the entire baseline mean was substituted in order to calculate the percent reduction. [c] Actually, when reduction percentage is calculated by comparing end-of-treatment with end-of-baseline, as was done for both the Carr et al. data and the Israel et al. data in Table 8, all 60 participants did 4% better than the normal 90% reduction standard requires. They all achieved a 94% or greater reduction from baseline.

Changes in trends (slope of acceleration or deceleration) before and after CSS introduction

Change effects that occur in data series such as those of Figure 1 can consist not only of jumps (sudden frequency changes) that are seen where trends change, but also of celeration turn downs or celeration turn ups. A celeration turn means that there is an inflection at the end of a trend at which a change in the ongoing acceleration or deceleration takes place. A celeration turn down means that one of three things takes place at the inflection point: (1) the slope of acceleration changes to a different acceleration that is less steep; (2) an acceleration changes into a deceleration; or (3) the slope of a deceleration changes to one that is even steeper. A celeration turn up means that one of these three things takes place at the inflection point: (1) the slope of acceleration changes to a steeper acceleration; (2) a deceleration changes into an acceleration; or (3) the slope of a deceleration changes to one that is less steep.

For 49 of the participants there was no opportunity to examine the celeration turns because their charts show a jump down to zero or near-zero frequencies immediately after CSS introduction. Of the remaining 11, Table 9 describes each participant's treatment data by the jumps and turns that occur. Each major change effect is labeled as to week number, and is characterized by its jump (a "jump up," "jump down" or "no jump") and celeration turn (a "turn up," "turn down," or "no turn."). In each description, the effect that occurred immediately after CSS was inserted is described first. If there were additional major changes after that, each of these is also described and delimited with semicolons.

As can be seen in Table 9, the decelerative power of CSS is evidenced by the jumps and turns that occurred right after CSS was first inserted. All 11 showed jump downs at CSS introduction. And after those jumps, only 1 of the 11 participants showed a celeration turn up, 3 showed no change in trend (i.e., showed no turns) and 7 showed celeration turn downs.

Table 9

Changes in Frequency Jumps and Celeration Turns after CSS Introduction for Participants who did not Show Jump Downs to Zero or Near-zero

Participant #	Change Effect Description
6	Jump Down, Turn Down (wk 49);
16	Jump Down, No Turn (wk 70); No Jump, Turn Down (wk 104); No Jump, Turn Up (wk 117)
24	Jump Down, No Turn (wk 93)
27	Jump Down, Turn Down (wk 95); No Jump, Turn Down (wk. 116, at change from GED-1 to GED-4)
28	Jump Down, Turn Down (wk 96)
30	Jump Down, No Turn (wk 104)
36	Jump Down, Turn Up (wk 109); No Jump, Turn Down (wk 135, during treatment)
37	Jump Down, Turn Down (wk 114)
48	Jump Down, Turn Down (wk 136)
50	Jump Down, Turn Down (wk 139)
59	Jump Down, Turn Down (wk 150)

Comparison of overall improvement of high and low functioning participants

We divided the participants into two groups according to level of cognitive functioning and compared the improvement of the two groups. We used two different methods for classifying each participant as either higher or lower functioning, and analyzed the data separately for each method.

Results when MR diagnosis was used to classify participants. In Table 10, the improvement shown by participants who had been diagnosed with MR is compared with those who were not so diagnosed. For the 28 participants *without* an MR diagnosis, the medians of their individual mean weekly frequencies during baseline and treatment phases were 25.2 and 0.06 respectively. This represents an overall improvement (reduction) by a factor of 25.2 ÷ 0.06 = 420 which is a reduction of 99.8%. For the 32 participants *with* an MR diagnosis, the medians of their individual mean weekly frequencies during baseline and treatment phases were 98.5 and 0.64 respectively. This represents an improvement (reduction) by a factor of 98.5 ÷ 0.64 = 154, which is a reduction of 98.4%. In other words, the non-MR participants showed 420÷154 = 2.7 times more overall improvement (decrease) than did the MR participants. An overall reduction of 100% was achieved by only 38% of the MR group, but by 68% of the non-MR group. A reduction of 95% or greater was achieved by 81% of the MR group, but by 100% of the non-MR group.

Table 10

Improvement of MR and Non-MR Participants

	MR	Non-MR
1. No. of Participants	32	28
2. Median of the Individual Mean Weekly Frequencies (All Baseline Weeks)	98.5	25.2
3. Median of Individual Mean Weekly Frequencies (All Treatment Weeks)	0.64	0.06
4. Overall Reduction from Baseline (Divide-by-Factor) Calculated as Row 2 divided by Row 3	154	420
5. Overall Reduction from Baseline (Percent) Calculated as (Row 2-Row 3)÷Row 2	99.4%	99.8%
6. Percent Achieving 100% Overall Reduction	38%	68%
7. Percent Achieving 95% or Greater Overall Reduction	81%	100%
Superiority of CSS with Non-MR group = 420 ÷ 154 = 2.7 times greater overall reduction from baseline		

We completed a χ^2 analysis with respect to two variables: MR classification (MR vs. No MR) and chart classification from Table 4 (the number of students achieving a zero or near-zero reduction vs. the number in all other classifications). In Table 11, these data are presented. The result of the analysis was significant, χ^2 (1) = 13.13, $p < .001$.

Table 11

Frequency Table of MR and Chart Classification

	MR	No MR	Total
No. classified as achieving zero or near-zero reductions from Table 4.	20	28	48
No. in all other classifications from Table 4.	12	0	12
Total	32	28	60

Results when conversation skill was used to classify participants.

As a second approach, we ignored the participants' diagnoses, and classified them informally as either higher or lower functioning according to whether or not they could carry on a meaningful conversation with a normal adult. Five JRC staff members, who knew the students well and who were unaware of the purpose of the categorizations, made these judgments independently. The final assignment of each student to a group was determined by majority decision.

The results based on this conversational skills standard are presented in Table 12. A total of 38 participants were judged to be high functioning by this standard. They engaged in a median (of the individual mean weekly frequencies) of 28.56 aggressive behaviors during the baseline period and a median (of the individual mean weekly frequencies) of 0.07 aggressive behaviors during the treatment period. This represented an improvement (reduction) by a factor of 408. The 22 participants who were judged to be low functioning by this conversation skills standard displayed a median (of their individual mean weekly frequencies) of 94.83 per week and 1.37 per week, respectively, during baseline and treatment phases. This represented an improvement (reduction) of ÷ 69.9. The high functioning participants showed 5.8 (408 ÷ 69.9) times more overall improvement (decrease) than did the low functioning group.

An overall reduction of 100% was achieved by only 14% of the low functioning group, but by 68% of the high functioning group. A reduction of 95% or greater was achieved by 73% of the low functioning group, but by 100% of the high functioning group.

Need for emergency takedown restraints before and after CSS introduction

We compared the number of emergency takedown restraints that participants underwent during the 30 days immediately prior to CSS introduction with the number they underwent during the 30 days immediately after CSS introduction. Figure 4 shows this data. Figure 4 does not show successive calendar days on its horizontal axis. This axis shows days prior to, and subsequent to, CSS introduction. Irrespective of on what calendar day, during the 3-year period, each takedown restraint occurred, we totaled, across all 60 participants, all emergency takedown restraints that occurred on the 1st day *before* CSS introduction, all that occurred on the 2nd day *before* CSS introduction, etc. The data point immediately to the *left* of the intervention line in Figure 4 represents the total for the 1st day before CSS introduction, the data point that is second to the left from the intervention line is for the 2nd day before CSS intervention, etc. We also totaled all emergency takedown restraints that occurred on the 1st , 2nd , 3rd ,

Table 12

Improvement of Low and High Functioning Participants (Using an Informal Judgment of Conversation Skills to Determine Level of Functioning)

	Low	High
1. No. of Participants	22	38
2. Median of the Individual Mean Weekly Frequencies (All Baseline Weeks)	94.83	28.56
3. Median of the Individual Mean Weekly Frequencies (All Treatment Weeks)	1.37	0.07
4. Overall: Reduction from Baseline (Divide-by-Factor) Calculated as Row 2 divided by Row 3	69.9	408.0
5. Overall: Reduction from Baseline (Percent) Calculated as (Row 2-Row 3)÷Row 2	98.6	99.8
6. Percent Achieving 100% Overall Reduction	14	68
7. Percent Achieving 95% or Greater Overall Reduction	73	100

Superiority of CSS with high functioning group = 408 ÷ 69.9 = 5.8 times greater overall reduction from baseline.

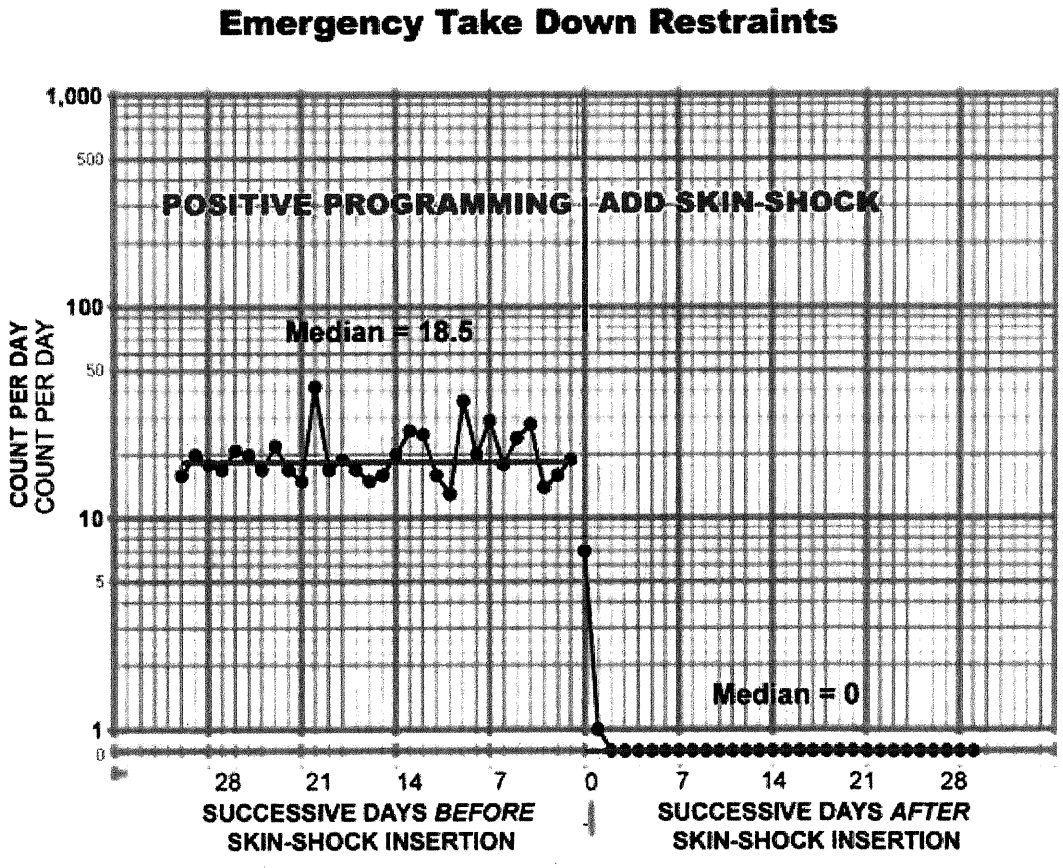


Figure 4. Emergency takedown restraints for the 30 days before and after the introduction of skin-shock.

etc. day *after* CSS introduction and these totals are shown in the first, second, third, etc. data points that appear to the *right* of the intervention line.

The participants, as a group, had a median of 18.5 emergency takedown restraints per day during the last 30 days before CSS introduction and a median of 0 emergency takedown restraints per day during the first 30 days after CSS introduction. Because each takedown restraint involved the joint action of 2-8 staff members, as well as one other staff member whose only role was to observe the restraint, and because each instance was recorded on a restraint form at the time of the restraint, measures to insure interobserver reliability were not deemed necessary.

Use of Psychotropic Medication

Forty-eight of the 60 participants (80%) were taking a total of 159 psychotropic medications when they enrolled at JRC. We measured the total number of participants taking psychotropic medications and the number of medications they were taking at the following points in time: (1) when the participants enrolled at JRC (2) when CSS was introduced; and (3) when the participants left JRC, or December 1, 2007 for those who still resided at JRC on that date. Both the date of enrollment and the date of departure (or on December 1, 2007 for those who were still at JRC) were, for some participants, outside of the 3-year window within which the aggression data reported above was obtained. The results are summarized in Table 13. By the date on which CSS was inserted, the number of *participants* taking psychotropic medications had already been reduced by 64.58%. By the date on which the participants departed from JRC (or on December 1, 2007 for those who were still at JRC), the number of participants taking psychotropic medications had been reduced by 93.75%. The total number of psychotropic *medications* that were being taken by participants had been reduced by 74.21% by the time of CSS introduction and by 97.48% by the time the student left JRC (or by December 1, 2007, for those still at JRC).

Table 13

Use of psychotropic medications

	On Date of Enrollment		On Date of CSS Introduction[a]		On Departure Date or 12/1/07, whichever earlier		
	No.	Percent of all 60 participants	No.	Reduction (Percent)	No.	Reduction (Percent)	Reduction (Divide-by-Factor)
Number of participants taking psychotropic medications	48	80.00%	17	64.58%	3	93.75%[b]	48/3 = ÷16
Number of psychotropic medications being taken.	159		41	74.21%	4	97.48%[c]	159/4 = ÷39.8

[a]In those cases in which the GED-1 was used first and was later switched to the GED-4, the date of the GED-1 introduction was used. [b]One participant stopped receiving CSS treatment on 6/25/06, after the end of the 3-year period of this report (the school district removed CSS from his IEP on grounds that it was a methodology, not an IEP objective) and resumed one psychotropic medication on 6/24/07. If this student is not counted, the percentage reduction would be 46/48 = 95.83%. [c] If the student mentioned in table footnote b (who stopped receiving CSS treatment on 6/25/06 and who resumed one psychotropic medication on 6/24/07) is not counted in the calculation, the percentage reduction would be 98.11%.

Comparison of injuries to staff members before and after CSS introduction

We compared the number of injuries that the participants caused to staff members by their aggressive behaviors during baseline with the number they caused during treatment. These were significant injuries that required nursing or other medical attention. For example, during baseline the following injuries were recorded: bites (50), contusions (bruises) (39), strains (18), head injuries (11), sprains (10), lacerations (4), pains (3), abrasions (3), headaches (2), temporomandibular joint problem (1), exposure to blood-born pathogens exposure (1), nasal injury (1), nasal fracture (1), tooth fracture (1), cracked tooth (1). The data is shown in Table 14. Injuries decreased from 146 before CSS introduction to only 7 after. The number of injuries per participant-month, after CSS introduction, decreased by a factor of 25.5, which was a 96% reduction.

Table 14

Aggression-caused injuries to staff members

	No. of Staff Injuries Caused by Participants	No. of Participant -Months	Injuries per Participant -Month
Baseline phase	146	615	0.2274
Treatment phase	7	751	0.0093
Decrease (divide-by-factor)			÷ 25.5
Decrease (percent)			96%

DISCUSSION

This retrospective analysis represents the largest set of data that has been reported on the effects of CSS on aggression. A total of 109.3 person-years (5,685 person-weeks, 39,795 person-days or 955,080 person-hours) of continuously recorded data on aggression are reported. Our results suggest that CSS delivered from the GED, when used as a supplement to a comprehensive behavioral program that involved powerful and consistent reinforcement and educational procedures, was extremely effective in decelerating aggressive behaviors to zero or near-zero levels and in maintaining the behaviors at those levels for periods of up to three years.

The only two treatment outcome reviews that have addressed the treatment of aggressive behaviors are those of Cataldo (1991) and Carr (1999). Unfortunately, although the Cataldo review surveyed 137 studies, only 3 of these studies, involving only 4 participants, dealt with the use of CSS to treat aggression. The low percentage (60%) that reached treatment effectiveness (90% or greater reduction from baseline) found in those studies may have been due to factors such as an inadequately robust CSS stimulus, lack of consistent treatment, and/or insufficiently powerful positive programming procedures.

In the present study, positive behavioral education and treatment, supplemented by CSS, proved to be approximately twice as effective in treating aggression as were the positive behavior support procedures reviewed in the Carr et al. 1999 report. By "twice as effective" we mean that 100% of our participants reached treatment effectiveness (90% or greater reduction from baseline) as compared with only 55.5% who achieved this in the Carr et al. report. Two factors make the superiority of the present results all the more notable. First, the treatment projects reviewed by Carr et al. had been chosen by their authors for submission for publication. Authors of such studies rarely submit failures or negative results for publication. By contrast, in the present study no selection of participants was made. Every single participant whose program was supplemented with CSS during a 3-year period was included with the exception of 7 who were absent from the treatment for such long periods that they did not receive a

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consistent treatment program, four other because of logistical difficulties in obtaining consent, and 1 guardian who declined to participate. Second, most of the participants in the present study probably had substantially more severe behaviors than those in the Carr et al. review because they had all previously been rejected, expelled or tried without success in programs that rely solely on positive behavior support procedures (see Israel, Blenkush, von Heyn, & Sands, 2009).

The finding that the positive programming/CSS combination used in the present study almost doubled the effectiveness (in terms of the percentage that reached the 90% or greater reduction standard) that was found in the positive behavior support papers reviewed by Carr et al. is important because many persons and agencies—such as TASH and the Association for Positive Behavior Support—assert that even the most severe problem behaviors can be effectively treated with Positive Behavior Support methods alone (TASH, n.d.; APBS, 2007). Using or choosing a treatment that is 50% less effective than would otherwise be possible might be justified if the aggressive behaviors to be treated are not severe. If the aggression is severe, however, and might result in serious harm to others or to the individual him/herself, choosing a relatively ineffective treatment over one that has proven to be twice as effective raises its own ethical issues.

Because the number of GED applications was always fewer than the number of aggressive behaviors that were tallied, Table 6 can be used to set an outside limit on the number of GED applications that were applied to consequate aggression. Using this data, one can see that no more than 3,764 applications of the GED-1 and GED-4 were made for these 60 participants during the 3 years in question. The median participant received fewer than 0.14 applications per week, which is approximately 1 application every seven weeks. The range was from 0 per week (e.g., participant 29) to 12.15 per week (participant 27). In some cases the number of applications necessary to control the participant's aggression was remarkably low. Participants 19, 44, 54, 55, 56, 57, and 60 did not receive any applications at all after the first week. Participants 2, 10, 11, 31, 33, 34, 39, 42, 45, 52 received only 1 or 2 applications after the first week.

The failure to find significant adaptation in most of the participants is noteworthy. For almost all participants, aggressive behaviors remained at a low level, or continued to decelerate over time, even when the CSS contingency remained in place for periods of up to three years. This finding is significant in light of previous reports of adaptation associated with SIBIS, the skin-shock device that has been used in most CSS studies during the past 17 years (e.g., Ricketts, Goza, & Matese, 1993; Williams, Kirkpatrick-Sanchez, & Iwata, 1993).

A possible limitation of this study was the lack of interobserver reliability. Due to financial considerations, these measures were not obtained. However, it is important to note that those who counted aggressive behaviors completed a significant amount of training and there were various mechanisms within the program to maintain treatment integrity, including live and video monitoring of the staff by trained supervisors. Additionally, the data were collected across environments and represent a complete picture of the total daily behavior frequency of each participant as opposed to session data. Although gradual removal or fading of the GED was possible for many participants (38%), CSS treatment may, for some individuals with significant developmental disabilities, be prosthetic, i.e., required on a long-term basis—as is the case with eyeglasses, hearing aids, prosthetic limbs, and many drugs—rather than curative. An appropriate prosthetic device or environment enables a behaviorally handicapped individual to behave normally in a normal environment (Lindsley, 1964) and markedly enhances the individual's quality of life.

Our results suggest that CSS was effective not only with lower functioning individuals, such as those with severe or profound retardation and autism, but also with individuals with normal or near-normal cognitive functioning. When presence or absence of an MR diagnosis was used to determine level of functioning, CSS proved to be almost three times more effective in overall reductive power with higher

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as compared with lower functioning participants. When, instead, an informal conversation skill standard was used to determine level of functioning, CSS was almost six times more effective in terms of overall reductive power with higher functioning participants than with lower functioning participants The greater effectiveness of CSS with the higher functioning participants was probably due to the fact that for these participants their aggressive behaviors were modified not only by the direct application of contingencies, but also because their superior verbal behaviors enabled their aggression to be affected by rule-governed behavior (Skinner, 1969) as well.

This finding that CSS was more effective with the higher functioning participants may be true of other punishers as well. Foxx and Livesay (1984), for example, found that "higher functioning individuals treated with overcorrection showed longer and better treatment effects than lower functioning individuals"(Foxx, 2003, p.11). A more detailed analysis of the differential effect of CSS on individuals with differing cognitive levels and verbal skills merits future study.

Detection of the superior overall decelerative effect of CSS on the aggression of higher functioning participants was made possible by examining the factor by which the baseline value divided rather than by examining the percentage reduction. For example, in Tables 10 and 12, if one compares only the percentage reduction of the higher versus lower functioning participants, the small differences seen—0.4% when the criterion was presence or absence of an MR diagnosis, and 1.2% when it the standard was an informal assessment of conversational skills—do not reflect the true difference in decelerative power of CSS as between the two groups. Only when we compared the decreases of the two groups by using the reductive factors does the greater improvement for higher functioning participants become clear. Graf and Lindsley (2002) have cautioned researchers against the weaknesses of percent as a measure.

The practice of employing skin-shock with "higher functioning" individuals has been criticized by some. These concerns should be weighed, however, against the fact that some of the higher functioning participants in the present study, unlike many of the lower functioning participants, have been able, with the temporary help of this treatment, to turn their lives around, live independently and become future taxpayers. Many of them function at a level where they can discuss their treatment and reflect on its value to them, something several of them have done at public hearings before Massachusetts legislative committees that have considered bills that would ban the use of skin-shock as a behavioral treatment.

Despite the fact that we administered up to 3,764 GED applications to the participants, the only negative side effect found was an occasional temporary discoloration of the surface of the skin that cleared up within a few minutes or a few days. The most common immediate collateral behavior associated with the application of skin shock was a temporary tensing of the body that some participants showed while the application was applied. Other collateral behaviors were avoidance responses such as attempts to remove the device or grab the transmitter, and temporary emotional behaviors. Future research should be devoted to the prevalence and mitigation of collateral behaviors associated with skin shock.

The absence of negative side effects of CSS treatment with the GED has been confirmed by van Oorsouw, Israel, von Heyn, and Duker (2008), who found either significant improvement or no change in positive verbal and nonverbal utterances, negative verbal and nonverbal utterances, socially appropriate behaviors, and off task behaviors.

The procedures used in this study eliminated the need to use emergency takedown restraint with the participants. The number of such restraints, when totaled across the entire group of 60 participants, dropped from a median of 18.5 per day before CSS introduction to a median of 0 per day after. Each such restraint lasted between 20 and 120 minutes and involved from 2-8 staff members. From the participant's perspective, the elimination of such takedowns avoided the humiliation that can be involved in

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undergoing them, and resulted in large savings of time that could now be devoted to classroom learning instead of to being restrained on the floor. Duker and Seys (2000, 1996) have also reported the reduction of restraint as a product of the use of CSS.

By eliminating the need for emergency takedown restraints, CSS treatment enhanced the participants' safety by enabling them to avoid a procedure which, when not carried out properly, can be dangerous. The reported number of deaths in the United States each year due to the use of manual or mechanical restraint has been estimated to be in range between 50 and 125 per year, with some estimates even higher (Conner, 2006). The figure for injuries is probably many times higher.

Our data also shows that the type of behavioral treatment reported here made it unnecessary, in most cases, to continue to use psychotropic medication to control aggression. This fact also enhanced the safety of the participants in this study. Chyka (2000) summarized the number of deaths caused by adverse drug reactions (to psychotropic medications) in 1995 as reported by the US Food and Drug Administrations (FDA). He found that 848 people died as a result of such reactions. This number does not include deaths or other injuries due to human error in medication administration.

It should be noted that these two dangerous procedures—psychotropic drugs and emergency takedown restraint—both of which can be avoided by using the procedures described in this report—are two of the most common procedures that programs normally use to deal with severe aggression.

Anecdotally, we observed other positive side effects. Once the participants' aggression diminished, a cascade of other positive results began to follow naturally. Participants began succeeding, sometimes for the first time, in passing their behavioral contracts. As a result, they began to earn more rewards, advance to residences and classrooms with more privileges, and generally improve their quality of life. Their parents and siblings began to take them home and for outings more often. Many participants were now attending school and learning new skills for the first time in years. Many began to make meaningful plans for finishing public school, obtaining further education, obtaining competitive jobs, and leading a normal, institution-free lives.

Paradoxically CSS, whose application caused some temporary discomfort, had the longer-term effect of improving the participants' self-concept, outlook, safety, and happiness when it was used as a supplement to a powerful positive behavioral program to treat aggression as well as other major problem behaviors. During the treatment phase, many of participants in this report developed optimism for their future where previously there had been none. Faces that appeared to have a permanent scowl when they had first enrolled at JRC, were now relaxed, happy, and smiling. Many who had arrived at JRC with depression found that this was no longer a problem when they were behaving well, earning frequent rewards, and achieving goals. In some cases the participants' improved behaviors even enabled them to lose their previously stigmatizing diagnoses.

The beneficial effects of supplementary CSS treatment were so clear that some participants in this study *asked* to be able to go on GED treatment because they could see how much the quality of life had improved for other participants who had already started the treatment. It is not an exaggeration to state that for many of these participants supplementary CSS treatment helped them to turn their lives around and orient them in a positive direction. Future research should be directed to examining these anecdotally noted effects in a scientific fashion.

These observations are consistent with the reports that the effectiveness of CSS in reducing problem behaviors tends to be associated with a wealth of positive side effects (Linscheid et al., 1990; Matson & Taras, 1989) and that the positive side effects tend to far outnumber any negative side effects associated with CSS (Salvy et al., 2004; Linscheid, Pejeau, Cohen, & Footo-Lenz, 1994; Linsheid et al., 1990; Matson & Taras, 1989; Carr & Lovaas, 1983). Future studies should seek to quantify these positive changes.

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Seven Case Studies of Individuals Expelled from Positive-Only Programs

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Abstract

In the debate over aversives a little-known but significant fact is often overlooked: programs that restrict themselves to positive-only treatment procedures sometimes expel individuals with severe behaviors when their behaviors become too difficult to handle. We review seven such cases of individuals with severe behavior problems who were expelled from state-of-the-art, positive-only programs and describe what happened to them when they were enrolled in a program that was able to supplement its positive-only procedures with contingent skin-shock when necessary.
Keywords: severe behavior, skin-shock, aversives, positive behavior support

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Many problem behaviors of special needs individuals can be satisfactorily treated with "positive-only" behavioral treatment procedures. By "positive-only" we mean behavioral procedures that do not include physical aversives. Support for the effectiveness of positive-only procedures in treating many individuals can be found in a comprehensive review by Carr et al. (1999). They showed that in 50% of the studies that qualified for their review, the behaviors were successfully treated (using a standard of achieving a 90% reduction from baseline) with positive-only procedures, and that this figure rose to 60% when the cases reviewed were limited to those in which a functional analysis was performed.

Despite the fact that 40-50% of the cases in the Carr et al. (1999) report were not effectively treated, proponents of positive-only programming continue to assert that *all* severe problem behaviors can be managed successfully with positive-only procedures. For example, the TASH presents the following information on their website, "Positive strategies for changing behavior work equally rapidly, work with behaviors that are equally severe, and are at least as effective as strategies that are aversive or coercive in nature." (TASH, n.d.) The Standards of Practice of the Association for Positive Behavior Support, as displayed on the Association's web site as of November 2007, stated, "Positive strategies are effective in addressing the most challenging behavior." (APBS, 2007)

Foxx (2005) made two important points in response to these assertions: (1) in many of the papers that claim to report successful treatment with positive-only procedures, the behaviors were not very severe; and (2) in at least one paper, the author failed to disclose the significant role that psychotropic drugs played in the result.

The present paper presents a third point relating to the assertion that positive-only treatment can effectively treat all behavior problems, including the most severe ones: *when programs using positive-only procedures encounter individuals with really difficult-to-treat behaviors, they sometimes reject or expel them.* It is important to expose this fact because otherwise both lay and professional people will be misled by such assertions concerning the effectiveness of positive-only treatment.

This paper presents seven brief case histories of individuals who were expelled by behaviorally-sophisticated, positive-only programs when their behaviors became too difficult to manage. All seven were subsequently admitted to the Judge Rotenberg Educational Center (JRC), a program that is able to supplement positive-only procedures with a contingent skin-shock aversive when required. For a

description of the treatment procedures employed at JRC, see Israel, Blenkush, von Heyn, and Rivera (2008).

The positive-only programs that expelled the seven individuals discussed below, are all well-regarded schools in which any parent would be fortunate to be able to enroll his or her special needs child. Several of them use state-of-the-art behavioral procedures, employ skilled behavior analysts, and have had the benefit of nationally-known consultants in behavioral programming.

All information and quotations provided below have been taken from referral documents provided to JRC as part of the normal enrollment process for each of the individuals involved. In each case, the parents of these individuals have granted permission to JRC to use their child's information in this paper[1]. The individuals whose data are displayed will be referred to as Students 1, 2, 3, etc. and the schools as School A, B, C, etc.

Student 1

Between the ages of 7 and 15 Student 1 was a resident at School A, a well-regarded behavioral special needs program that uses positive-only procedures. While Student 1 attended School A, his aggressive behaviors were described in his 2005 Discharge Summary as "quite intense and non-redirectable," and included "head directed punches, head butts, hair pulling, kicking, grabbing and biting." Student 1's aggression and self-abuse were so frequent that he had to be restrained "more than 70" times per week and each restraint required up to five teachers. His self-injurious behaviors included "body hits to the environment, head hits to wall and floor, body punches, face or head hits, self-bites" and hand contortions (intense wringing of hands and fingers). These behaviors caused "bruises, scratches, swelling of joints, cuts to forehead caused by intense head-to-floors (while wearing a protective helmet)...[and] fractured bones in his hands on two occasions." Property destruction included throwing objects, ripping materials, turning over furniture, and throwing large heavy objects. His aggressive behaviors, such as hitting his mother while she was driving, prevented him from having any home visits and curtailed community outings from School A.

School A tried many "positive-only" treatment approaches without success. They gave Student 1 rewards of small snacks, breaks, and preferred activities throughout the day contingent on appropriate behaviors or on the completion of certain tasks. They taught Student 1 functional communication responses, in which he used language to request being alone, to get teacher attention, or to escape demands. They tried using restraint as a positive reinforcers for desired behaviors. They provided Student 1 with periods of no demands and periods of high-rate demands. At one point Student 1 received 1-1 staffing during all waking hours. School A made use of internationally-recognized experts in the behavioral treatment of severe aggression to help design Student 1's positive-only program. In addition, School A tried Student 1 on psychiatric medications such as Risperdal, Trileptal, and Seroquel. None of these steps were sufficiently effective.

In March, 2005, School A expelled Student 1. His Discharge Summary explained the reason as follows: "At this point, behavior-control medication and treatment approaches based on positive reinforcement have been generally unsuccessful in producing long-lasting decreases in Student 1's behavior. This suggests that Student 1 may require alternative interventions than those normally used at [School A], for example, mechanical restraint or contingent aversive stimulation."

In March 2005, at age 15, Student 1 was admitted to JRC. Figure 1 is a chart showing combined monthly totals of Student 1's aggressive, health dangerous, major disruptive, destructive, and noncompliant behaviors.

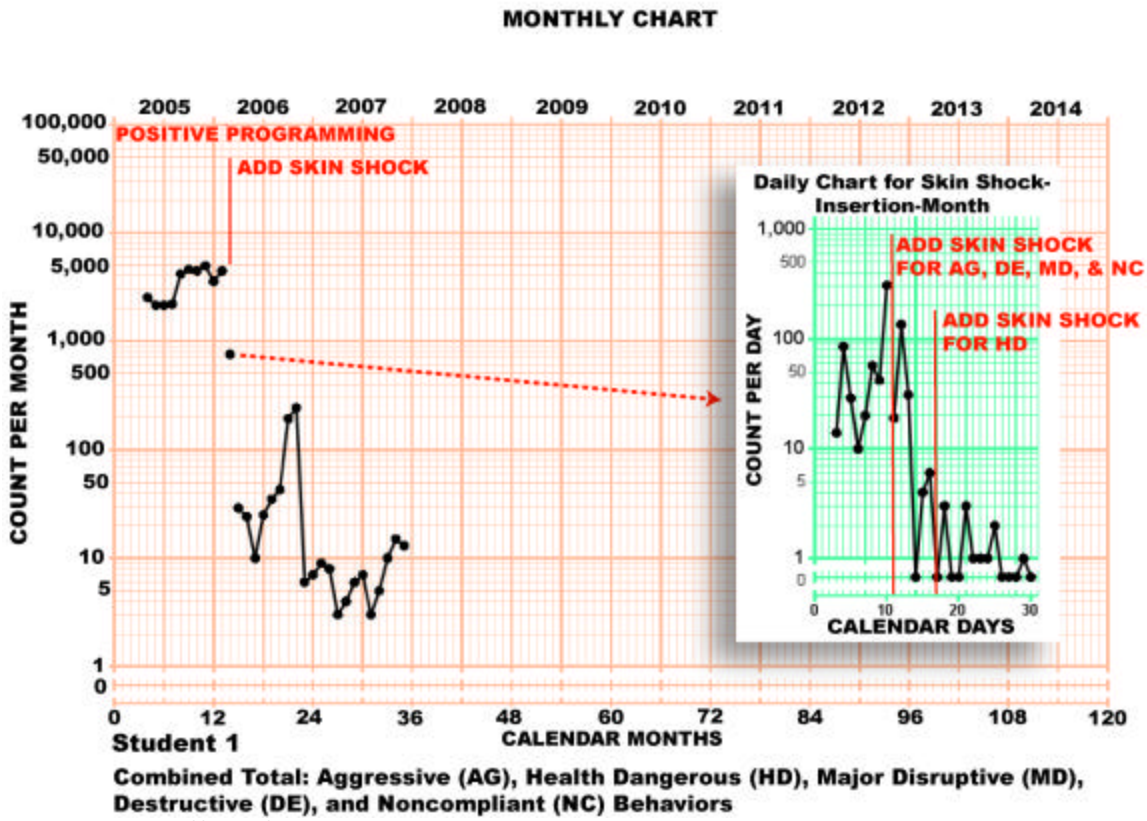


Figure 1. The effect of contingent skin-shock on the aggressive, health dangerous, major disruptive, destructive, and noncompliant behaviors of Student 1.

The chart is the same[2] as the monthly version of the Standard Celeration Chart (Pennypacker, Guiterrez & Lindsley, 2003) except that it displays only 5 of the usual 6 cycles. The chart has a multiply/divide scale on the vertical axis. A relative change, such as a doubling, tripling or halving, occupies a constant up-down distance anywhere on this chart. The data on which this chart is based were recorded by JRC's direct care staff members and then entered into a database. Computer software then produced daily (see inset graph in Figure 1), weekly, monthly (Figure 1) and yearly charts with multiply/divide scales which were updated daily and accessed by Student 1's clinician at his desktop through the school's network.

The data series displayed on the left side of Figure 1 is divided into three parts: (1) a data series for the 10 months of baseline (labeled "Positive Programming"); (2) a single data point for the month during which the skin-shock was inserted in the student's program (the "skin shock insertion month"); and (3) a data series for 21 months of skin-shock treatment. The data point for the skin-shock insertion month is not connected to either the baseline or treatment series because it contains some days from the baseline phase and some from the treatment phase.

To show the data for each of the days of the skin-shock insertion month there is a daily chart that is inset on the right side of the chart[3]. This chart is basically the same as the daily Standard Celeration Chart (Pennypacker et al., 2003) except that it shows only 3 of the usual 6 cycles.

Figure 1, as well as the other behavior charts included in this paper, shows the number of behaviors that the individual in question engaged in, and not the number of skin-shock applications, which was always less. One reason is that sometimes the individual displayed many instances of certain behaviors within a single episode. In such cases each separate behavior occurrence was tallied and

recorded, but only one skin-shock application was given to consequate the entire episode. Another is that on some occasions, due to equipment failure or other reasons, an alternative consequence (a verbal "No") was substituted for the skin-shock.

During Student 1's first 10 months at JRC, psychotropic medication was tapered and discontinued, and positive-only programming was used exclusively. Figure 1 shows, however, that JRC's positive-only programming was not successful by itself in decreasing Student 1's problem behaviors. Over the course of his first 10 months at JRC, he displayed a mean of 3,532 aggressive, health dangerous, major disruptive, destructive, and noncompliant behaviors per month and the behaviors were accelerating.

After these first 10 months, during which JRC's positive programming proved unsuccessful, Student 1's parents gave their approval to JRC to supplement his positive programming by arranging a single skin-shock consequence for each instance of his problem behaviors. For more information on JRC's positive-only programming procedures and its use of supplementary skin-shock delivered by the Graduated Electronic Decelerator (GED) device[4], see Israel et al., (2007). After obtaining prior parental informed consent, and with various other safeguards in place (Israel et al., 2008), JRC applied to a Massachusetts Probate Court for approval of an individual treatment plan for Student 1 that included the use of skin-shock. This procedure of obtaining prior parental consent as well as an individual court authorization for skin-shock treatment was also followed in each of the other cases presented in this paper.

The data for the first month of treatment are displayed in the inset daily chart on the right side of Figure 1. Notice that CSS treatment of health dangerous behaviors (labeled "HD" in the inset) began one week after CSS treatment was started for the other four categories of behavior—aggressive (AG), destructive (DE), disruptive (DI), and noncompliant (NC). The relatively high rates seen during the first few days of CSS treatment reflect the continued high rate of Student 1's health dangerous behaviors, which were not yet being treated with CSS.

Once skin-shock was added to Student 1's program for all of his major problem behaviors, the behaviors showed an abrupt drop in monthly frequency, changing from 4,459 during the last full month of baseline data to 29 during the first full month of CSS treatment—a decrease in which the frequency divided by a factor of 154. In calculating this drop, immediately after CSS insertion, for Student 1 (and for the other students covered in this paper) we ignored data from the skin-shock insertion month, because it was composed of data from both the baseline and treatment phases. A sudden frequency drop that occurs immediately after the introduction of skin-shock is often found when CSS, generated by the GED device, is employed and is seen in other charts in this report. See Israel et al. (2008).

In the 21 months since skin shock was started with Student 1, the rate of his major problem behaviors has remained at a manageably low level. Although his problem behaviors are not at zero, his most recently monthly frequency was only 13 as compared with 4,459 in the final baseline month.

As a result of this dramatic decrease in Student 1's problem behaviors, by April, 2006, he was able to participate in weekly academic and recreational field trips to places such as restaurants, art centers, the zoo and bowling alleys. He was able to complete his bathroom routine independently and had learned to brush his teeth with only verbal prompts. As of this writing, Student 1 works independently on his computer academics and completes most of his household chores without the need for prompts. His family now enjoys successful visits with him at JRC and takes him into the community on those occasions.

Student 2

In 1999, at age 13 Student 2 enrolled in a day school operated by School B, another well-regarded special needs program that uses positive-only behavioral treatment procedures. At that time she engaged in head-banging to the point of causing pain, redness, bruising and tissue damage. She did this by either hitting her head against an object or by punching her head or face with her fist. She averaged 15-23 occurrences per day. While at School B, the severe punching of her own eyes caused permanent impairment of her vision. She also flopped on the floor from a standing or seated position and aggressed against other students as well as staff members. Her aggressive behaviors included grabbing, pinching, scratching, and pushing others. At home, Student 2's sister was terrified of her because of her behaviors, and as a result Student 2 could not participate in family trips.

School B treated these behaviors using the following positive-only procedures: they tried to block all of her self-injurious behaviors; they prompted her to put her hands down if necessary; they stopped interacting with her until she remained calm for ten seconds; they encouraged her to use her "words" instead of exhibiting her problem behaviors; they granted any request during times she was not exhibiting her behaviors; they gave her a functional communication book and they also used manual restraint in the form of certain "protective holds." On the school bus they kept a row of empty seats as well as an aisle between Student 2 and the nearest other person. In addition, the psychotropic medications Buspar and Risperidone were tried without positive effects. Student 2's last IEP from School B shows that her self-injurious behaviors, even after 5 years of positive-only treatment, were occurring approximately 23 times per day.

In April 2004, School B expelled Student 2. Shortly thereafter, at age 17 she was admitted to JRC. Figure 2 is a monthly chart showing Student 2's aggressive, health dangerous and noncompliant behaviors, all combined into one monthly total.

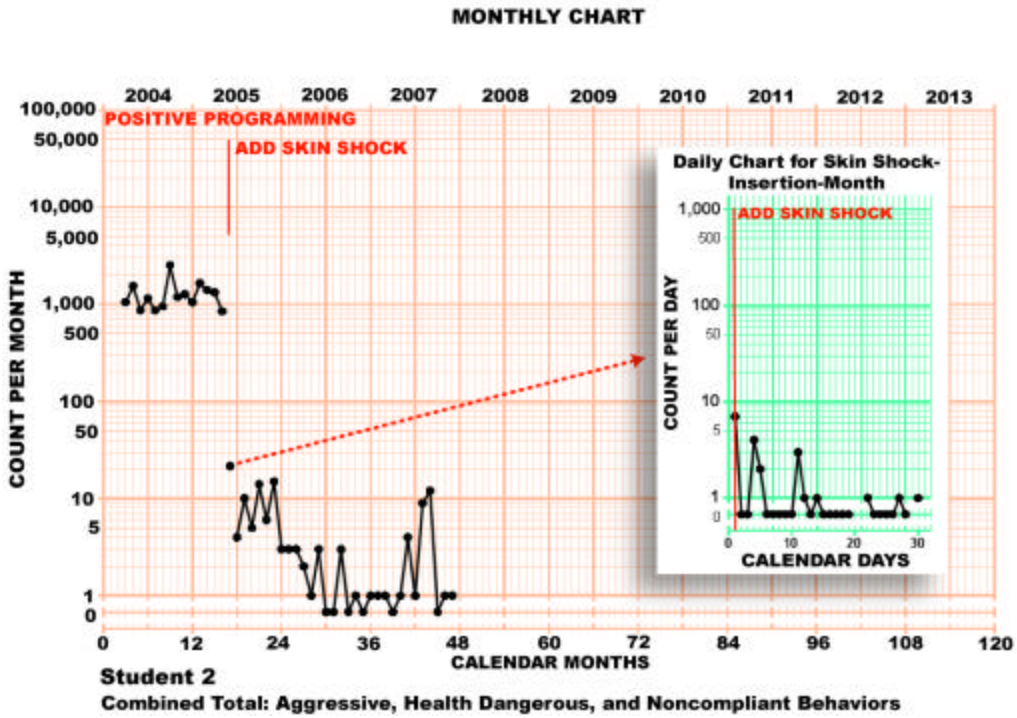


Figure 2. The effect of contingent skin-shock on the aggressive, health dangerous, and noncompliant behaviors of Student 2.

During her first fourteen months at JRC, Student 2 was treated with positive-only programming. This was not effective in decreasing her major problem behaviors which, after fourteen months, were still occurring at unacceptably high levels (mean of 1,994 per month during the last three baseline months).

In May 2005, JRC added a skin-shock intervention to Student 2's program to treat her aggressive, health dangerous, and noncompliant behaviors. Figure 2 shows that once the skin-shock consequence was added, her aggression, self-abuse, and noncompliance decreased abruptly. After skin-shock insertion, and ignoring the data from the skin-shock insertion month itself, Student 2's problem behaviors dropped from 848 per month (last full baseline month) to 4 per month (first full treatment month)—i.e., divided by a factor of 212. Those behaviors then decelerated further over the next 2 ½ years, except for a sudden frequency increase ("jump up") in July 2007 and a sudden frequency decrease ("jump down") in September 2007, and reached 0 or 1 during each of the last 3 months shown on the chart.

Student 2 now engages in academics for extended periods and is able to move from one area of the school building to another without problems. She works on academic programs that are teaching her to count and is making significant progress in her communication skills. Her sister is no longer afraid of her. As a result, Student 2 has been able to participate in a family vacation to Florida. All of this would have been impossible if her problematic behaviors had remained at frequencies similar to those she exhibited during her first 14 months of positive-only programming at JRC.

Student 3

Between the ages of 14 and 17, Student 3 attended School A (the same school that Student 1 and Student 5 had attended) as a residential student. According to a discharge summary in 2003, while Student 3 was enrolled there, he displayed "noncompliance, aggression to others, sexualized behavior, self-injury and property destruction," behaviors that occurred "across the day at the school and residential settings…". He often required 3:1 or 4:1 staffing and was often restricted to a special intensive unit where students received 24-hour 1:1 staffing. During his stay at School A, there were numerous documented incidents in which he required medical attention as a result of self-injurious behaviors or fighting with his peers. He exhibited severe aggressive behaviors, including physical altercations with his peers, as well as self-injurious behaviors such as punching his head, running away and cutting into his right arm. In addition, Student 3 displayed inappropriate sexual behaviors and swearing at staff. During several home visits, Student 3 either ran away from home or would engage in physical altercations with his family members. After one of his fights with his father, Student 3 had to be placed in handcuffs by the police and taken to an emergency room.

When Student 3 exhibited these problematic behaviors, the primary techniques that School A employed were "physical intervention," placing him in "exclusionary time out" (seclusion) and restricting him from "community and vocational environments for varying amounts of time depending on the topography of the behavior." Positive interventions utilized while at School A included: offering choices, visual supports, verbal and physical prompting, environmental modifications, behavioral contracts (DRAs), a point system, direct instruction, and consultative services from a speech and language pathologist. He was also placed on multiple psychotropic medications including Risperdal, Trazadone, Depakote, Neurontin, and Cogentin (earlier in his life he also been tried on Ritalin, Dexadrine, Clonidine, Tenex, and Thorazine). These treatment procedures were not sufficiently effective.

On October 20, 2003, Student 3's school district sent a referral packet to JRC inquiring if JRC was willing to accept him as a student. The referral letter from the referring school district to JRC stated, "As a result of his last IEP meeting it was decided that a more appropriate residential placement be found to address Student 3's complex needs."

Figure 3 is a monthly chart showing the frequency of Student 3's major problem behaviors at JRC.

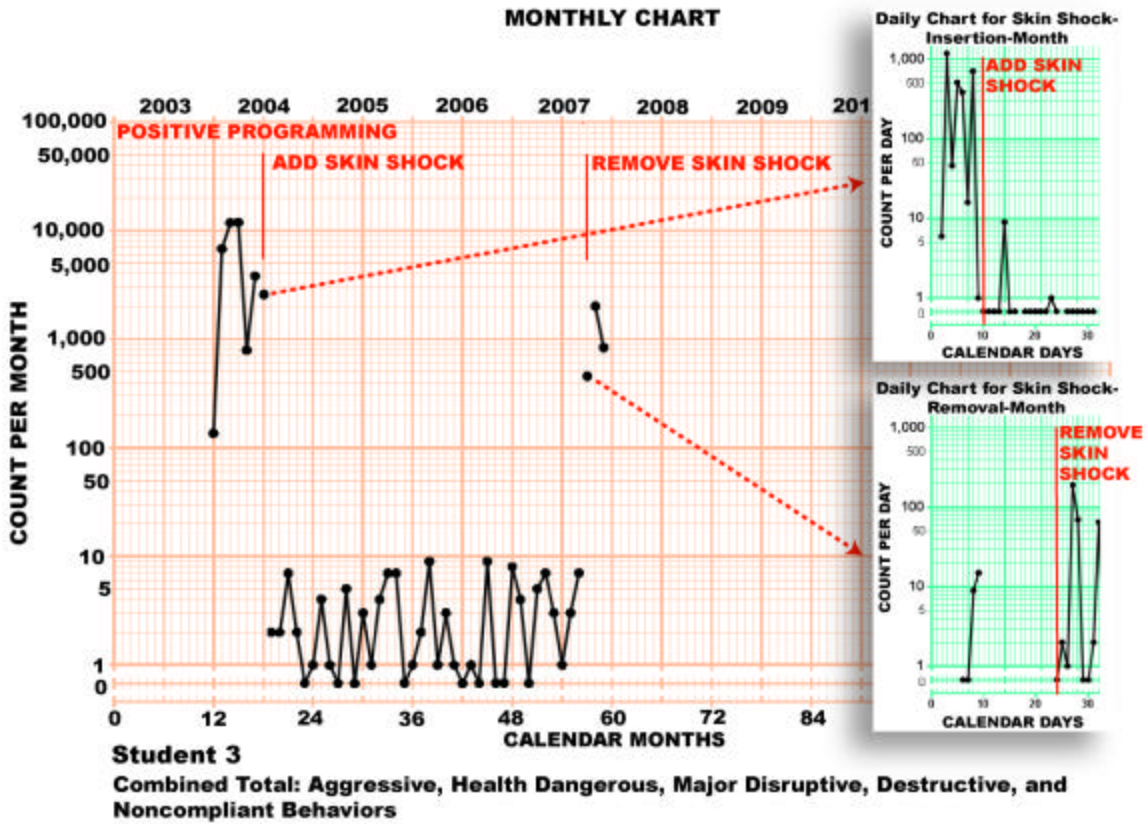


Figure 3. The effect of the addition and removal of contingent skin-shock on the aggressive, health dangerous, major disruptive, destructive, and noncompliant behaviors of Student 3.

These behaviors included aggressive, health dangerous, destructive, major disruptive behaviors and noncompliant behaviors. During Student 3's first six months at JRC, he received positive-only programming including, for example, various behavior contracts targeting the absence of inappropriate behaviors, as well as opportunities for him to earn various rewards throughout the day. During this period he was also slowly weaned off all of his psychotropic medication.

Student 3's problematic behaviors showed little improvement during his first five months at JRC. On month 6 he was still exhibiting 3,828 dangerous behaviors per month (a mean of 128 per day)—an unacceptably high level. There were some days, prior to the introduction of skin-shock, on which Student 3 would exhibit over 2,000 dangerous behaviors including aggression and sexually inappropriate behaviors.

In June of 2004 (daily data for this month is shown in the top inset graph) skin-shock was added as a consequence for Student 3's major problem behaviors. As soon as the skin-shock treatment was added to his program, Student 3 showed sudden and dramatic improvement. The frequency of his problem behaviors showed an immediate frequency decrease from 3,828 per month on the last full baseline month (and again ignoring the data for the skin-shock insertion month) to 2 per month on first full treatment month—an improvement by a factor of 1,914. After that, and for the next three years, Student 3's major problem behaviors maintained at a very low level, between 0 and 9 per month.

From the summer of 2004 through March 2007, Student 3 was able to work consistently each day on his academic skills in a classroom with his peers. He no longer hurt himself or others. He lived in an apartment with his peers that had minimal staffing, was learning vocational skills and went on several successful home visits.

In March, 2007 Student 3 ran away from JRC and when he returned his mother withdrew her permission (at Student 3's request) for the skin-shock treatment. Once this treatment was removed, Student 3's behaviors regressed to the same levels that he had shown at the end of his baseline period of "positive-only" treatment. The return of Student 3's problem behaviors as soon as skin-shock was removed shows how critical the skin-shock was for his improved behavior and suggests that for him it was functioning at that time as a prosthetic, rather than as a curative, treatment.

Currently Student 3 is doing poorly and his mother is now considering granting permission once again to JRC for the resumption of GED treatment.

Student 4

Student 4 enrolled in School C at the age of 5 in September of 1991. Student 4's self-injurious and aggressive behaviors increased in frequency and intensity as he grew older. Eventually his behaviors became so intense and unmanageable that neither he nor those around him were safe. Student 4 would physically attack others resulting in serious staff injuries. He would also head-bang. He bit himself so frequently that his hands became severely calloused. Because of his behaviors, he was unable to go on home visits, make community trips or receive an education.

School C did a careful functional analysis of Student 4's behavior problems and attempted to treat him with a wide variety of positive-only procedures which included the following: use of a picture schedule both in school and in the residence; use of a set of "first….then" sequence cards with him so that he could anticipate reinforcement; use of a timer so that he could recognize the beginning and end of activities; a sensory diet; instruction that was short, direct and brief; use of a penny board; use of a "break card" so that he could request a break at any time; use of communication book; and functional communication training.

In addition, Student 4 was given medications such as Haldol, Dexedrine, Orap, Thorazine, Risperdal, Depakote, Clonidine, Cogentin, Benydryl, Zoloft, and Luvox. Thorazine was also prescribed as a PRN, and if his behaviors failed to respond to the Thorazine another PRN of Trazodone was administered. None of these medications were effective.

School C eventually decided that it was unable to meet Student 4's needs and sought to refer him to some other program that might be better able to manage his behaviors. Every appropriate placement in his home state rejected Student 4 after reading his history. His information was then sent to 18 schools from Maine to Virginia. Only four of them called for interviews and he was rejected by all of them due to the intensity of his aggression.

A crisis period for Student 4 developed just prior to the point when he was discharged from School C. During this crisis, various additional interventions were tried, including retraining the staff that worked with him, providing 1:1 staffing at all times, psychiatric consultation, consultation with a well-known expert in autism, classroom changes, hospital outpatient psychiatric services, and PRN medications.

Eventually Student 4 was referred to JRC, which accepted him. In December of 2004, at age 19, Student 4 was discharged from School C and transferred directly to JRC. Upon arrival at JRC, Student 4

went into a coma due to an overdose of psychotropic medication that was given prior to and during his transportation to JRC. He was diagnosed with Neuroleptic Malignant Syndrome and was hospitalized for over 1 week.

Figure 4 is a monthly chart for Student 4 in which each data point represents the total of all of Student 4's most dangerous behaviors during that month.

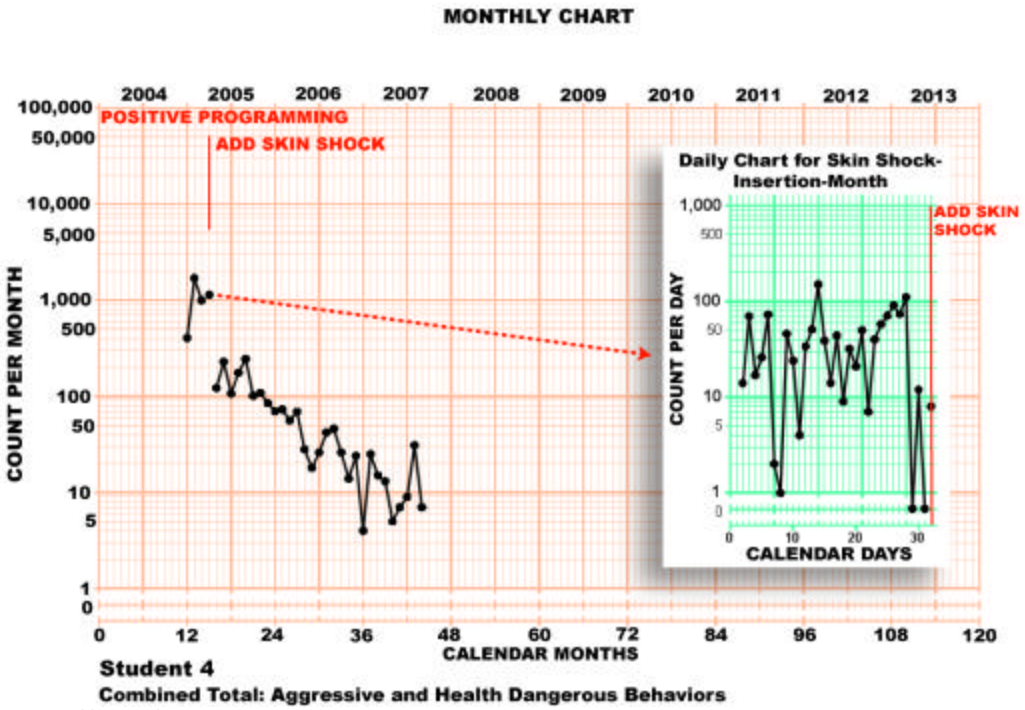


Figure 4. The effect of contingent skin-shock on the aggressive and health dangerous behaviors of Student 4.

The chart shows that during his first 3 months at JRC, during which he received positive-only treatment, Student 4 displayed a mean of 1,038 aggressive and health dangerous behaviors per month. Once contingent skin-shock was added to his program, (and ignoring the skin-shock intervention month shown in the inset), his problem behaviors made an immediate frequency jump down, dividing by a factor of approximately 6. The problem behaviors generally accelerated over the next four months, however, and then decelerated more or less steadily over the next 2 years.

Student 4 is now completely off all psychotropic medications and works daily on a computer doing his academic work. Student 4 has also made significant progress socially and with his daily living skills. He is able to participate in academic and recreational field trips, attends all school activities and goes out into the community with his parents when they visit, without any JRC staff accompanying him.

Student 5

Student 5 attended School A as a residential student between the ages of 10 and 14. While enrolled there, Student 5 engaged in severe aggression which was described in a referral summary from October 2001 as "head-directed punches, kicking, biting, spitting and throwing feces at others." He fractured a staff member's nose. His severe self-injury included head banging (against walls and objects) that required emergency sutures, "punching his eyes, hitting his head against objects, pulling his teeth out, biting himself, etc." He engaged in "property destruction, disrobing, clothes ripping, fecal smearing…elopement as well as other disruptive behaviors such as swearing, teasing and banging walls

and objects." On "two occasions he eloped during overnight hours when staffing was reduced." He also ingested inedible items, inserted objects into body orifices, showed noncompliance and engaged in tantrums. He punched his mother in the car, making transport home impossible, and he could not participate in community outings from school.

School A tried a variety of positive-only behavioral strategies. These included "positive reinforcement contracts," as well as "antecedent-based" types of interventions (manipulation of stimuli and setting events). At one point, after receiving expert consultation from a behavioral consultant, School A implemented new reward procedures as well as punishments. Contingent upon good behavior, Student 5 was allowed to a) select who would work with him on an hourly basis, b) choose from any preferred item or activity and c) request breaks and conversations at any time. In addition, surprise rewards were delivered on a variable-time schedule. Following certain maladaptive behaviors, Student 5's behaviors were consequated by providing him with complete (but non-preferred) meals and denying him any form of social attention until he exhibited 8 consecutive hours of appropriate behavior. This social isolation procedure was not effective. While attending School A, Student 5 was also given the psychotropic medications Risperdal, Tegretol, Trazodone and Benadryl, none of which were effective.

Student 5's referral summary reports that although School A's treatment procedures often showed promise at first, "these positive effects do not seem to maintain, and Student 5's aberrant behavior re-emerges…This has produced minimal positive change in [Student 5's] behavior." Decreases in target behaviors "haven't lasted more than one or two weeks."

In an IEP amendment dated 12/11/01, a representative of School A wrote that the sending school district proposed amending his IEP to change his place of education. The reason was given was that "… his behavioral issues are becoming more significant and putting his safety at risk. Also [School A] have given the district's [sic] until Feb. 1st 2002 to transition [Student 5] to another placement" [bracketed material supplied].

On March 5, 2002, at age 14, Student 5 was enrolled at JRC. Figure 5 is a chart showing the monthly totals of Student 5's five major categories of problem behaviors – aggressive, health dangerous, destructive, major disruptive and noncompliant–combined into one monthly total.

See Figure 5, Next Page!

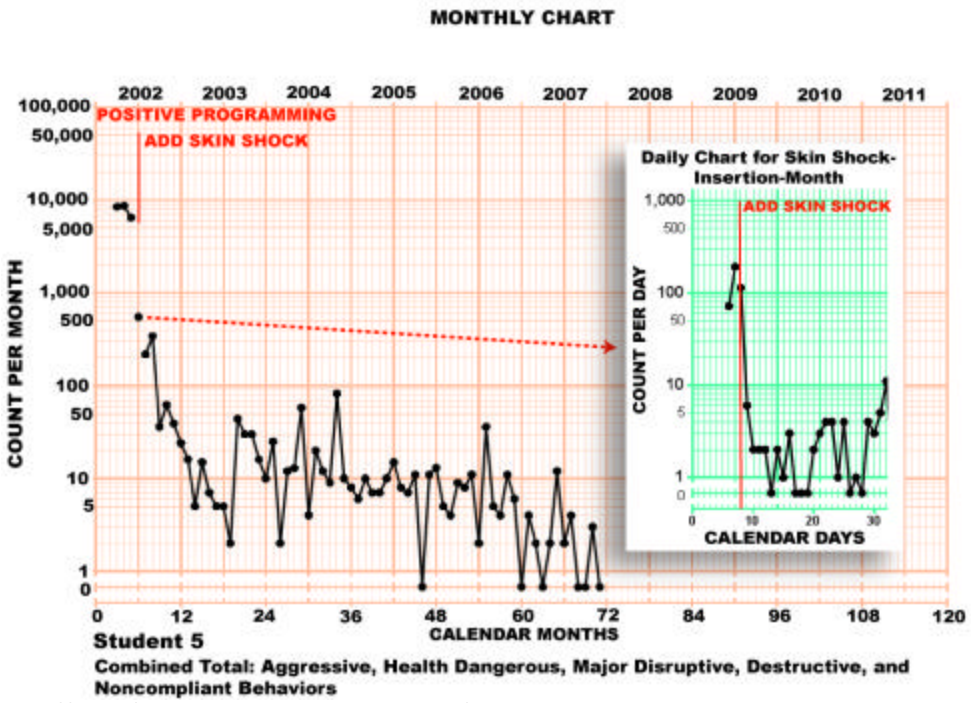


Figure 5. The effect of the addition and removal of contingent skin-shock on the aggressive, health dangerous, major disruptive, destructive, and noncompliant behaviors of Student 5.

During Student 5's first four months at JRC, psychotropic medications were tapered and discontinued, and positive-only programming was applied. Although this programming succeeded in dropping his major problem behaviors from a frequency of 8,626 per month to 6,502 per month, this was still an unacceptably high level.

In June of 2002 JRC added a skin-shock intervention to his program, with the usual prior parental consent, individual court authorization and other safeguards. Figure 5 shows that this addition to Student 5's program was associated with an immediate frequency jump down. Once again, we ignore the skin-shock insertion month (which includes both baseline and treatment days), whose daily data is shown in the inset, in calculating this jump down. The monthly frequency dropped from approximately 6,502/mo (on the last full baseline month) to 218/mo (on the first full treatment month)—i.e., divided by a factor of 30. Over the next five years, these behaviors showed a general deceleration, reaching zero in November 2007.

Student 5 now rarely requires physical restraint and consistently masters academic lessons in reading, math, phonics and spelling. He lives with another student in an attractively decorated room which he does not damage. He enjoys field trips (educational and recreational) and no longer has difficulties with transitions. Student 5 continues to learn new and appropriate social behaviors that have allowed him to form relationships and interact appropriately with his support staff, family and other students. He now goes on frequent, successful overnight home visits with his parents.

Student 6

In September 1997, Student 6, at age 14, displayed such severe aggressive and health dangerous behaviors that no residential program would accept him. As a result, he was placed in a children's hospital. Due to his lack of any behavioral progress while there, in December 1999 the hospital sent him

for a four month evaluation to School D, another well-regarded special needs residential program that specializes in positive-only treatment. His most problematic behaviors while attending School D included scratching himself, rubbing his body parts together to cause injury, biting himself, pinching himself and hitting/banging his head. Due to his self-abuse, Student 6 had numerous scars on his body and had required surgery on his left ear. Student 6 would also become aggressive if staff prevented him from injuring himself.

School D's interventions to treat Student 6 included mechanical restraint for almost the entire day, and immobilization at night. He was even prevented from moving while in bed in order to help him sleep better. Despite all this mechanical restraint Student 6 continued to engage in self-abusive and aggressive behaviors.

In March 2000, Student 6 was discharged from School D and sent back to the children's hospital from which he had come. The hospital continued the use of the restraint that had been developed at School D and later, due to his continued aggressive and self abusive behaviors, added the psychotropic drugs Droperidol and Cogentin. His mother reports that during his time at School D Student 6 was unable to go home, was out of control, and received no meaningful education.

At age 17, in October 2000, Student 6 was admitted to JRC. At that point he was in mechanical restraint and still receiving Droperidol and Cogentin. Whenever Droperidol, an anesthetic, was administered to him, Student 6 fell asleep. He was weaned very quickly from the psychotropic medications because they appeared to have no therapeutic value in view of the fact that he still exhibited intense and dangerous behaviors when awake. At JRC Student 6 was started immediately not only on positive programming, but also on court approved contingent skin-shock, because he was continuing to cause severe damage to his face even while wearing arm splints and a helmet.

Figure 6 shows the combined monthly totals for Student 6's aggressive and health dangerous behaviors.

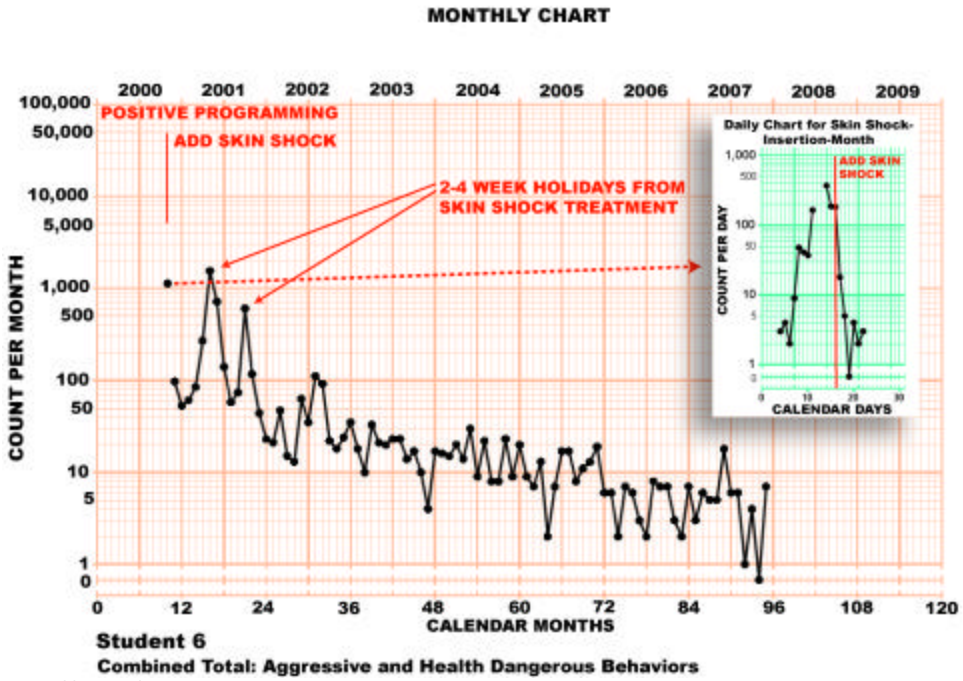


Figure 6. The effect of contingent skin-shock on the aggressive and health dangerous behaviors of Student 6.

Within one week of the addition of skin-shock treatment, JRC was able to remove his helmet and began fading the stiff stays out of his arm splints. As Figure 6 shows, after the introduction of skin-shock treatment, Student 6's maladaptive behaviors showed an initial deceleration followed by two distinct spikes in behavior. During these two periods skin-shock treatment was temporarily suspended for a few weeks because his records indicated that he had a history of displaying occasional dramatic increases in behaviors that were resistant to treatment. During these periods mechanical restraint was used to keep him safe. When CSS treatment was resumed, Student 6 showed a gradual and relatively steady deceleration that has extended over seven years. During the last month shown in Figure 6 he displayed zero problem behaviors.

Student 6 is now flourishing academically and socially. He is free of all restraint and medication. He averages only one self-injurious behavior per week and is a happy, smiling young man, free of any injuries. No restraint or medications are necessary and he participates in a full schedule of academics, habilitative skill development and vocational training. He participates in activities in the local community and enjoys frequent visits from his mother.

Student 7

Student 7 was enrolled in special education programs starting at the age of 5, when he attended a day program operated by School E. Student 7's mother reports that he was out of control while there and frequently ran nonstop around the classroom. During a weekend respite stay at School E, Student 7 opened a bottle of liquid Mellaril and drank the entire bottle. He ended up in the emergency room and on the pediatric unit of a hospital for three days. Student 7 was discharged from School E after one year because he was not making any progress and his inappropriate behaviors were increasing.

Student 7 was then admitted to the same School A that is referred to above. At that point he was engaging in 70-80 aggressive and self-injurious behaviors per day. His most severe behaviors included biting himself and others, bolting from staff, pinching himself and others and pica. He was discharged from School A after 1 year because he was not making progress and his behaviors were increasing.

Student 7 then spent 7 years at School F. School F's interventions included the use of group dynamics, art, music, academics and the acquisition of communication and daily living skills. During Student 7's stay at School F, he made significant progress in learning daily living skills but his severe maladaptive behaviors impeded continuous growth in all other areas. He would often have tantrums involving violent aggressive outbursts and health dangerous behaviors such as frequently bolting from teachers and engaging in pica. Student 7's mother was unable to control his severely dangerous behaviors when he was at home during vacation periods. He would stay awake during the night hours and engage in pica, ingesting household items such as motor oil, detergents, bleach, plants, lead paint and deodorant. On one occasion, Student 7 assaulted his brother while his bother was driving a moving vehicle. During Student 7's vacation periods he repeatedly chewed on the woodwork in his mother's house.

School F was unable to treat Student 7 successfully and at age 12 he was removed and enrolled in School G. While at School G the frequency and intensity of his dangerous behaviors began to increase. He recurrently targeted younger children and females with intense aggression, often biting and scratching them. These outbursts were sometimes without antecedents and appeared premeditated. He would wait for the staff member or peer to turn his or her back to him and then aggress. Antecedents or situations likely to bring about behavioral outbursts included placing demands on him, telling him "no", and denying him a food item that he desired. Because he attacked his family when at home, he could not go on regular home visits or on community trips with them.

One of the principal interventions used at School G involved escorting him to a secluded area

subsequent to an aggressive or health dangerous episode and prompting him into a seated position. In this area he often would bite his hand or bang his head while moaning. On several occasions it required additional staff support to contain him in this area because he attempted to assault the staff. If these episodes occurred while at his group home, Student 7 would be escorted to an empty room and be left unattended. Once there, he often destroyed the blinds in the room, bit himself and continually got out of his seat. In addition Student 7 engaged in frequent disruptive and noncompliant behaviors such as screaming, refusing to follow directions or respond to physical prompts, disrobing, and masturbating in public. While at School G, he was prescribed Risperdal, which was also unsuccessful in treating his behaviors.

In April 2003, Student 7, now age 16, was admitted to JRC. Figure 7 shows the monthly totals of Student 7's most dangerous behaviors.

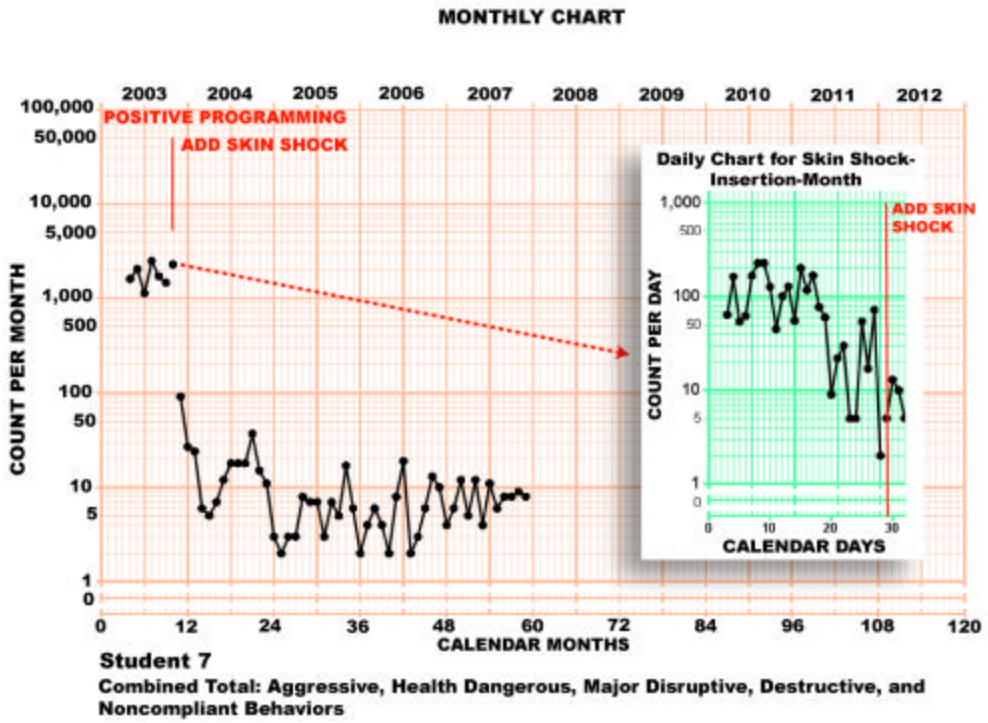


Figure 7. The effect of contingent skin-shock on the aggressive, health dangerous, major disruptive, destructive, and noncompliant behaviors of Student 7.

When Student 7 was admitted to JRC he was treated with positive-only programming for over six months. During this period there was no deceleration in his problem behaviors and he was engaging in a mean of 1,753 dangerous and disruptive behaviors per month. After these six months of positive-only programming, contingent skin-shock was added to Student 7's treatment. Student 7's health dangerous, aggressive, destructive, major disruptive and noncompliant behaviors then showed an immediate decrease. If we once again ignore the skin-shock insertion month shown in the inset, the jump down is from 1,476 per month (last full baseline month) to 92 per month (first full treatment month), dividing by a factor of 16. Thereafter the behavior decelerated over the next 15 months to 2 or 3 per month. During the last three years he has exhibited a mean of only 6.8 problem behaviors per month.

In addition to these behavioral improvements, Student 7 advanced academically and socially. As

of October, 2003 when skin-shock was inserted into his program, Student 7 was able to participate in community outings and weekly field trips to places such as museums, amusement center, and restaurants and was able to go on frequent home visits with his family.

Discussion

All seven individuals presented in this paper were expelled from highly regarded behavioral programs that used state-of-the-art positive-only programming. All seven eventually required that their positive-only programs be supplemented with an effective aversive stimulus in the form of skin-shock. When skin-shock was added, all seven made significant academic and social progress and were able to engage in the positive rewards and educational progress to which they had previously been denied access due to the frequency and intensity of their dangerous behaviors. These case histories provide strong support, therefore, for using supplemental aversives when positive-only interventions have failed to produce appropriate results and the individuals are at continued risk of harming themselves or others.

These reports also suggest that the assertion that all severe problem behaviors can be effectively treated with positive-only behavioral treatment procedures is premature. Until positive-only procedures are able to treat individuals with really severe behavior problems effectively, and without disabling and harmful psychotropic drugs, it is only prudent and humane to keep available the option of supplementing positive procedures with aversives when required.

Unfortunately, during the past few decades, considerations of political correctness, career advancement, and regulatory prohibitions have prevented most behavioral psychologists from considering, using or even doing research on supplementary aversives. Where does this leave parents of children such as those described above, whose children have been rejected or expelled from the best positive-only programs available and whose behaviors are too dangerous for the children to be taken home? And where does this leave the individual who is stuck with a problematic, non-functional repertoire that our current technology of positive-only procedures is unable to remedy, who is facing a lifetime of dangerous psychotropic medication while bouncing in and out of psychiatric hospitals or other institutional settings, and who has lost the opportunity to participate in a rewarding and meaningful life?

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Footnotes

[1] Copies of the documents containing the quotations contained in this document, as well as related information, are available from the senior author upon request.

[2] As is true of the monthly Standard Celeration Chart, on this chart a data series that doubles every six months draws a 34 degree angle.

[3] The reader may wonder why the first data point on this inset daily chart is not placed on the first vertical line. On this daily chart the heavy vertical lines represents Sundays, and the thin vertical lines represent the weekdays. Each data point is plotted on the day of the week appropriate to the date on which the student displayed that total number of problem behaviors.

[4] For an analysis of the side effects of JRC's skin shock treatment, see van Oorsouw, Israel, von Heyn & Duker (2008).

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RUNNING HEAD: Risk-Benefit Analysis

A Risk-Benefit Analysis of Antipsychotic Medication and Contingent Skin Shock for the Treatment of Destructive Behaviors

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Abstract

Antipsychotic medications are commonly used to address destructive behaviors in people with developmental disabilities. Contingent skin shock is less commonly employed. Here, the risks and the benefits of antipsychotic medication and contingent skin shock are enumerated and compared. First, the major untoward effects of antipsychotic medications and contingent skin shock are summarized. Second, an efficacy analysis was conducted consisting of the following components: a brief description of the conclusions of a 1991 review of antipsychotic medications; a complete analysis of the effect of first generation and second generation antipsychotics on the irritability subscale of the Aberrant Behavior Checklist; a complete analysis of first generation and second generation antipsychotics on the Clinical Global Impression – Improvement Scale; a complete analysis of the effect of first generation antipsychotics, second generation antipsychotics, and contingent skin shock on destructive behavior frequency. The results of the analysis suggest that contingent skin shock is by far the most effective procedure and has the most favorable side effect profile.

Keywords: destructive behaviors, antipsychotic, contingent skin shock, risk-benefit analysis, aggression, self-injury

A Risk-Benefit Analysis of Antipsychotic Medication and Contingent Skin Shock for the Treatment of Destructive Behaviors

Clinical teams comprised of psychiatrists, behavior analysts, and other professionals strive to provide the least restrictive most effective treatment to those people with developmental disabilities who exhibit destructive behaviors. Each discipline has expertise in a range of interventions. For example, the behavior analyst may be skilled is assessment of behavior function, differential reinforcement, extinction, and punishment procedures. On the other hand, the psychiatrist brings a range of pharmaceutical interventions, the ability sign off on the use of protective equipment or mechanical restraint, and the acumen needed to recommend electroconvulsive therapy or psychosurgery.

Destructive behaviors generally include high intensity and/or high frequency aggression, self-injury, and/or property destruction, but may include other excessive topographies or idiosyncratic responses. High intensity means the behavior(s) result in injuries to the emitter, injuries to others, or requires emergency physical interventions or protective equipment. High frequency means the behavior occurs hundreds, thousands, or tens or thousands of times per day. Generally, these behaviors force the person to live away from their family home or ideal living situation, make it difficult or impossible for them to receive an education in a typical school setting or otherwise learn new skills, and result in frequent or long-term psychiatric hospitalization.

Differing opinions exists regarding how to employ the various interventions used to treat destructive behaviors. For example, Matson and LoVullo (2008) suggest using positive reinforcement methods, then adding aversives first and psychotropic medications second if necessary when treating self-injury. Wachtel and Hagopian (2006) suggested a cooperative

approach between psychiatry and behavior analysis in treating destructive behaviors exhibited by those with intellectual disabilities. Others have demonstrated successful treatment of destructive behaviors using differential reinforcement and punishment and, in most cases, eliminating medication (Israel, Blenkush, von Heyn, & Sands, 2010).

There is agreement that those treating people with destructive behaviors should provide the most effective and least restrictive treatment interventions available. Within behavior analysis and psychiatry, decision making models have been proposed to aid in clinical thinking regarding aversive interventions and psychotropic medications. For example, Meinhold and Mulick (1992) provided an example of a decision analysis that separated value statements from the effectiveness of treatment options, side effects, and costs associated with various interventions.

Mikkelsen (2007) proposed the following equation as a guide to clinical thinking regarding psychotropic medication and people with intellectual disabilities:

$$\frac{\text{Probability of Success} \times \text{Symptom Severity}}{\text{Side Effect Profile}} = \text{Hierarchy Quotient}$$

Mikklesen classified psychotropic medication side effect profiles into four categories based on extant literature, encouraged neutral data collection methods, and suggested examination of the literature and/or analysis of one's clinical experience to identify the probability of success of a particular drug intervention.

The models proposed by Meinhold and Mulick (1992) and Mikklesen (2007) share in common the need to identify the risks and benefits of treatment options. Treatment interventions that most would consider to possess minimal risk include function based behavioral interventions

based on positive reinforcement and pharmacological interventions with extremely mild side effect profiles. However, if such procedures are ineffective, the next set of treatment/management options include the following: frequent physical restraint; continuous mechanical restraint/protective equipment; antipsychotic medication and polypharmacy; and contingent skin shock. In addition, psychosurgery (Mpakopoulou et al., 2008) and electroconvulsive therapy (Wachtel et al., 2009) have been described.

In 1989, the National Institute of Health held a consensus development conference to examine destructive behaviors and associated treatments in people with developmental disabilities. The final report was controversial (Foxx, 2004) and called for more research. Since 1989, new treatments and new information regarding existing treatments has been published. New atypical antipsychotic drugs including clozapine, risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, and paliperidone were introduced in the United States in 1989, 1994, 1996, 1997, 2001, 2002, and 2006 respectively. Increasingly, these medications have been prescribed to address destructive behaviors exhibited by people with developmental disabilities. New information about contingent skin shock is also available.

In this paper, the efficacy and side effect profiles of first generation antipsychotic medication (FGA), second generation antipsychotic medication (SGA), and contingent skin shock (CSS) are summarized and compared.

Side Effect Profiles

Side Effect Profile of First Generation Antipsychotic Medications

The side effects of FGA include acute extrapyramidal syndromes, chronic extrapyramidal syndromes, neuroleptic malignant syndrome, weight gain, sexual dysfunction, seizure, prolactin level elevation, and sudden cardiac death, among other side effects.

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Marder and van Kammen (2005) describe acute extrapyramidal syndromes including akathisia, dystonia, and drug induced parkinsonism. Akathisia may be characterized by a feeling of inner restlessness, inability to sit still, or urge to walk or initiate movement. Akathisia has been reported to occur in 62% (41% - mild; 21% - moderate to severe) of those taking FGA. Acute dystonias consists of muscle spasms of the head and neck and involuntary movements. These reactions occur in 40% of those treated with high potency FGA who do not also receive antiparkinsonian medications. Finally, drug induced parkinsonism, comprised of rigidity, bradykinesia, shuffling gait, and tremor, occur in approximately 30% of those chronically treated with FGA. Anticholinergic medications are often effective in treating extrapyramidal side effects but are associated with an additional set of side effects. Extrapyramidal signs have been reported to occur in children treated with FGA at percentages ranging from 25-73% (Aronson, 2009).

Casey (1990) summarized the clinical presentation of tardive dyskinesia (TD) in the following way:

> Tardive dyskinesia is characterized by repetitive, involuntary, purposeless movements. The typical signs include chewing; tongue protrusion; vermicular tongue activity; lip smacking, puckering, and pursing; or paroxysms of rapid eye blinking. Choreoathetoid movements in the limbs and trunk can also occur. Dyskinesias in the fingers may look as if the patient is playing an invisible guitar or piano. Very rarely TD produces aerophagia, irregular respiratory rates, and grunting noises. (p. 535)

Generally, approximately 3% of those receiving typical antipsychotic drugs will develop persistent (lasting more than 3 months) cases of TD each year; approximately 2% per year will develop transient TD (lasting less than 3 months) (Tarsy, Lungu, & Baldessarini, 2011). Further, the cumulative incidence of TD has been reported at 5%, 27%, 43%, 52%, 56% at 1, 5, 10, 15,

20 years respectively (Tamminga & Woerner, 2002). If one does develop TD, reported recovery rates at 3 month have been reported at 24%, 40%, and 81% (Rosenheck, 2007). Generally, the probability of developing TD is related to age; with TD less common in children and adolescents and most common in the elderly.

Levinson (1985) described major and minor features of neuroleptic malignant syndrome (NMS). Major features include fever, rigidity, and elevated creatine phosphokinase concentration (suggesting injury or stress to the heart, brain, or muscle tissue). Minor features include tachycardia, abnormal arterial pressure, tachypnoea, altered consciousness, diaphoresis, and leukocytosis. The probability of developing NMS is estimated to range from .07%[1] to 2.2% per year (Adnet, Lestavel, & Drivosic-Horber, 2000). Marder and van Kammen (2005) suggest that 20 to 30% (or more) of well developed cases of NMS are fatal.

Allison et al. (1999) estimated the effects of FGA on weight gain in adults at 10 weeks of treatment. For the FGA's molindone, fluphenazine, haloperidol, chlorpromazine, and thioridazine, they found estimated mean weight changes of -.81, .43, .48, 2.10, and 3.49 kg respectively. Allison et al. noted that weight gain clearly increased with time and that patients taking the drugs for long periods of time would be expected to gain more weight. Aronson (2009) noted significant weight gain in nearly 100% of children treated with FGA (p.230). Obesity, of course, is associated cardiovascular diseases, diabetes, cancer, and other maladies (Wang, McPherson, Marsh, Gortmaker, & Brown, 2011).

FGA affect sexual functioning. Erectile dysfunction has been reported in 23 to 54 percent of men receiving FGA treatment (Marder & van Kammen, 2005). Sexual dysfunction varies among FGA. For example, Serretti and Chiesa (2010) found that perphenazine, haloperidol, and

[1] Gelenberg, Bellinghausen, Wojcik, Falk, Sachs reported using low does of neuroleptics as a possible contributing factor to the low frequency.

thioridazine were associated with sexual dysfunction in 25, 46, and 60 percent of patients respectively. They suggest that FGA may affect sexual function by inhibiting motivation and reward, increasing sedation, and reducing peripheral vasodilation.

Seizures have been reported to be associated with FGA. When examining incidence of seizures, Allredge (1999) pointed out that seizures have been reported to occur in the general population at an annual incidence of .073 to .086%. Aronson (2009) reports seizures to occur in probably less than 1% of those prescribed these drugs (p. 203). Logothetis (1967) compared seizure incidence in 859 patients treated with phenothiazines and 669 patients not so treated. Seizure incidence was equal to 1.2% for those treated with phenothiazines and 0.0% for those not treated with a phenothiazine. Seizures occurred in 9% of those prescribed a high dose (1000 mg/day or more of chlorpromazine or equivalent) compared to .3% prescribed a low dose (200 mg/day or less). On the other hand, Pauig, Deluca, and Osterheld (1961) found that seizures rates improved or remained unchanged in 64 of 100 patients with epilepsy receiving thioridazine.

Prolactin levels can be affected by FGA. Rosenbloom (2010) summarized studies describing the effect of antipsychotic medication on prolactin levels. A combination of 4 studies showed that of 56 children receiving a mean does of 7.2 mg/day of haloperidol, 90% had prolactin levels greater than the upper limit of what is consider to be normal. As a result 6.7% had gynecomastia and 15.4 had irregular menstrual cycles. A combination of 3 studies showed that of 46 children receiving 3.7 mg/day of pimozide, 80% had prolactin levels great than the upper limit of what is considered normal (reports regarding gynecomastia and menstrual cycles were absent). Madhusoodanan, Parida, and Jimenez (2010) summarized two studies showing a dose dependent increase in prolactin in 40-90% of those treated with phenothiazines. Crawford, Beasley, and Tollefson (1997) summarized the effect of haloperidol on prolactin levels of 69

adults and found 72% had elevated prolactin levels. In addition to contributing to galactorrhea, amenorrhea, gynecomastia, and sexual dysfunction, hyperprolactinemia may impact peak bone mass attainment and bone mineral density (Rosenbloom, 2010).

FGA have been associated with sudden cardiac death. Recently, Ray, Chung, Murray, Hall, and Stein (2009) summarized data associated with 90,307 (44,218 typical; 46,089 atypical) antipsychotic drug users and 186,600 matched nonusers of antipsychotic drugs between the ages of 30 and 74. They found higher rates of sudden cardiac death in users of FGA when compared to nonusers and reported incident rate ratios of 1.99 (95% confidence interval [CI], 1.68 to 2.34). Put another way, over the course of 1 year approximately 1 in 700 nonusers died of sudden cardiac death. However, for those prescribed FGA, over the course of 1 year approximately 2 in 700 died of sudden cardiac death. In addition, the risks varied with respect to drug and dose. For example, those prescribed high doses of thioridazine over the course of 1 person year, approximately 5 in 700 died of sudden cardiac death. The risk of sudden cardiac death was dose dependent as those receiving higher doses died more frequently than those who received lower doses. In addition, sudden cardiac death was 10 times more likely in the 70-74 age group compared to the 30-34 age group.

Sedation is a common side effect of FGA. Lehman et al. (2010), in the American Psychiatric Association Practice Guidelines for the Treatment of Patients with Schizophrenia, suggest the following: "Most patients experience some sedation, particularly with the low-potency first-generation agents such as chlorpromazine, but it occurs to some extent with virtually all antipsychotic medications." (p. 90)

Finally, typical antipsychotic medications have been associated with venous thromboemolism (Zornberg & Jick, 2000), hypotension, and QT prolongation (especially thioridazine) which potentially could contribute to sudden death (Aronson, 2009, p. 200).

Side Effect Profile of Second Generation Antipsychotic Medications

The side effects of SGA include acute extrapyramidal syndromes, chronic extrapyramidal syndromes, neuroleptic malignant syndrome, weight gain, sexual functioning, seizure, prolactin level elevation, among other side effects. Generally, SGA cause acute extrapyramidal side effects at similar rates when compared to low potency FGA (e.g. chlorpromazine, thioridazine) (Dayalu, 2008). Only case reports of acute dystonic reactions have been reported with SGA (Dayalu, 2008). Miller et al. (2008) reported that 37 – 44% of people taking olanzapine, quetiapine, risperidone, or ziprasidone met at least one of three criteria for parkinsonism for 1 year or less. They also described akathisia occurring in 26 – 35% of those treated with SGA.

In the past, SGA, in relation to FGA, were thought to be much less likely to cause TD. However, recent studies and reviews have not confirmed this assertion. In a recent review, Tarsy, Lungu, and Baldessarini (2011) concluded the following:

> The sparring of risk of TD with modern APDs [antipsychotic drugs] is surprisingly modest and less than is generally assumed. In fact, as reviewed above, TD risk may not be substantially lower than with some older APDs, especially those of low or moderate potency, including perphenazine, mesoridazine, molindone, and thioridazine. (pp 611-612; bracketed material supplied).

Correll and Shenk (2008) found annual TD rates of 5.5 and 3.9% respectively for FGA and SGA respectively. Woods et al. (2010) compared prevalence, incidence, and severity of TD in a 352 patient cohort who received treatment with antipsychotic medication between 2000 and 2005

with a 362 patient cohort who received treatment at the same mental health center in the 1980's (prior to the introduction of SGA). Despite the fact that only 36% received FGA in the 2000-2005 cohort, the prevalence, incidence, and incident case severity of TD were equivalent.

Troller, Chen, and Sachdev (2009) reviewed the literature related to SGA and NMS. They described NMS associated with all SGA and concluded that, with the exception of clozapine (which was less associated with rigidity), NMS induced by SGA looked the same as NMS induced by FGA. Finally, they noted that it was not clear whether any SGA was more or less likely to cause NMS when compared to FGA.

SGA have been associated with significant weight gain. For example, Allison et al. (1999) estimated that clozapine, olanzapine, risperidone, and ziprasidone were associated with weight increases of 3.99, 3.51, 2.00, and 0.04 kg respectively after 10 weeks of treatment. Correll et al. (2009) evaluated the effects of first time SGA treatment on weight gain in 272 children aged 4-19 years. After a median of 10.8 weeks of treatment, aripiprazole, risperidone, quetiapine, and olanzapine were associated with mean weight increases of 4.44, 5.34, 6.06, and 8.54 kg respectively. Those untreated gained a mean of 0.19 kg. Many of the drugs had a negative effect on metabolic parameters such as insulin, cholesterol, and triglycerides (among other parameters).

SGA have been associated with sexual dysfunction. Serretti and Chiesa (2010) summarized total sexual dysfunction reported in the literature regarding SGA. They reported clozapine, risperidone, olanzapine, aripiprazole, ziprasidone, and quetiapine to be associated with sexual dysfunction in 52, 43, 40, 27, 19, and 16% of patients respectively. However, they pointed out that, with the exception of risperidone and clozapine, rates of sexual dysfunction were lower in studies where concomitant use of other drugs was prohibited.

This risk of seizure associated with SGA is variable. Devinsky, Honigfeld, and Patin (1991) reviewed 1418 people treated with clozapine and found that 2.8% experience seizures (4.4% of those prescribed 600 mg per day or more; 1% of those prescribed 300 mg per day or less). Alper, Schwartz, Kots, and Kahn (2007) found clozapine and olanzapine to be associated with more frequent seizures upon examination of Phase II and III clinical trials.

Among SGA, risperidone is most likely to cause increases in prolactin. Upon review of the literature, Roke, van Harten, Boot, and Buitelaar (2009) found that risperidone, olanzapine, and quetiapine were associated with hyperprolactinaemia in 62, 31, and 12% of children respectively. On the other hand, clozapine and ziprasidone did not increase prolactin levels.

Ray et al. (2009) examined sudden cardiac death associated with clozapine, olanzapine, quetiapine, and risperidone. They found that these second generation drugs were associated with same degree of risk as first generation drugs and that risk was dose dependent. That is, within the sample of people aged 30-74, approximately 2 in every 700 people per year taking an SGA died of sudden cardiac death compared to 1 in 700 not taking an SGA or FGA.

Clozapine can cause agranulocytosis which is the suppression of bone marrow's production of infection fighting white blood cells (leaving the vulnerable to infection) (Crilly, 2007). In Finland, clozapine was originally introduced in 1975 to 2260 people. During that year, 16 (.70%) experience agranulocytosis and 8 (.35%) died as a result. de la Chapelle, Kari, Numinen, and Hernberg (1977) estimated the incidence rate at 2.1/1000 patient-months. Using their analysis, for every 80 people given clozapine for one year, 2 developed agranulocytosis and 1 in 80 died as a result. The introduction of regular blood tests and national patient registries significantly reduced the risk of agranulocytosis. For example, Honigfeld (1996) found that of

99,502 people receiving clozapine in the US between 1990 and 1994, .38% (378 people) experienced agranulocytosis and .01% (12 people) died as a result.

SGA have been associated with nocturnal enuresis. Harrison-Woolrych, Skegg, Ashton, Herbison, and Skegg (2011) evaluated the associated between nocturnal enuresis and clozapine, olanzapine, quetiapine, and risperidone people between the ages of 15 and 64. Enuresis occurred in 20.7 (17 of 82), 9.6 (11 of 115), 6.7 (7 of 105) , and 6.2 (12 of 195) percent of those taking clozapine, olanzapine, quetiapine, and risperidone respectively. For 65% of the participants, nocturnal enuresis occurred on multiple occasions.

Additional side effects, save weight gain, associated with SGA are presented in Tables 1-4. In these tables, the side effects reported in the studies examined for efficacy (described later in this paper) are summarized. In Table 1, the side effects, in the placebo controlled studies are presented. Every side effect, the number of times it was reported, the number of people in the group the side effect was reported in, and associated percentage are reported for drug and placebo groups. In Table 2, side effects such as sedation, somnolence, fatigue, etc. are grouped together and presented adjacent to placebo groups. Table 2 shows that 52% of those who received an SGA experienced some sedation/somnolence/fatigue type effect compared to 13% who were given placebo. Table 3 summarizes the side effects reported in studies without a placebo control. Table 4 shows side effects such as sedation, fatigue, somnolence, etc. from studies without a control group grouped together. For Table 4 and all tables, only the name of the first author is listed for the sake of brevity. Table 4 shows that 40 percent of those given an SGA experienced some sedation/somnolence/fatigue type effect.

Side Effect Profile of Contingent Skin Shock

In order to properly compare the side effects of contingent skin shock with the side effects associated with antipsychotic medications, it is important to classify side effects. There seems to be two kinds of side effects. First, there are specific side effects to the body. Second, there are side effects associated with behavior that were unintentional but beneficial or unintentional and disruptive or harmful. Here, all of these effects are reviewed with respect to CSS. However, it is important to point out that problem behaviors such as crying, escape behaviors, and noncompliance surrounding the administration of oral and/or intramuscular antipsychotic medication are not described in the typical drug study. Nor is the pain one experiences when medication is injected or venipuncture is required to monitor drug levels or side effects. Indeed, some children consider needles to be extremely painful and fear inducing (McMurtry, Noel, Chambers, & McGrath, 2011). In addition, examination of positive/negative changes in mood, learning, affection, appropriate behavior, inappropriate behavior are not necessarily part of typical side effect detection net for medications. This is not to say that such effects do not occur. Indeed, some researchers have noted improved response to behavior intervention plans [e.g. Frazier et al. (2010); Durand (1982)] with the addition of antipsychotic medications.

Matson and Taras (1989) reviewed 382 applied studies related to punishment (including studies with CSS as an independent variable) between 1967 and 1989. They found positive side effects were reported 212 times while negative side effects were reported 16 times. Here, the side effects found in CSS studies since 1989 are summarized.

The obvious effect of CSS is pain caused when the electrical current stimulates nociceptors and sensory receptors. The pain only lasts as long as the current is passing through the skin. Mudford (1995) reported superficial pin-point burn marks from sparks arcing from a

Hot Shot Sabre Six Device to the skin. This is the only device that is described to cause these tiny pinpoint burns. Mudford (1995) also reported a slight local tremor in the thigh during activation of a CSS device (Therapuetic Shock Device). Israel et al. (2008) reported the occasional discoloration of the skin remaining for a few minutes or days. Otherwise, no physical side effects have been reported

Negative behavioral effects have been reported. Duker and Seys (1996) described extreme anxiety (screaming, crying, attack, and escape) during the initial CSS treatment sessions in 5 of 12 participants. However, these responses subsided and only returned when the CSS device was removed from their body. They also described one participant who froze (made no responses) during the initial CSS treatment session. Duker and Seys (2000) describe providing relaxation training in the presence of panic or anxiety during the initial CSS presentation. Israel, Blenkush, von Heyn, and Rivera (2008) indicated some individuals emitted avoidance responses (such as removing the device or grabbing the transmitter). Other negative behaviors mentioned included temporary emotional behavior and tensing of the body.

The majority of the side effects reported in the literature associated with CSS are positive in nature. For example, Duker and Van den Munckhof (2007) found that heart rate increased (suggesting increased stress) when the CSS device was removed. Table 5 presents the positive behavioral effects derived from studies regarding CSS since 1989. Generally, decreases in problem behaviors not treated with CSS, improvements in appropriate behaviors, overt happiness, and improvement in skill acquisition are commonly described.

Efficacy

Overview of dependent variables

A number of different dependent variables have been used to measure the effect of FGA and SGA on destructive behaviors exhibited by people with developmental disabilities. The most common dependent variables are subjective ratings scales. Among the rating scales, the Clinical Global Impression – Improvement (CGI-I) scale (Guy, 1976) and the irritability subscale of the Aberrant Behavior Checklist (ABC-I) (Aman & Singh, 1986) are often used to describe the effect of a drug on destructive behaviors of the developmentally disabled.

The CGI-I scale instructions ask the rater (the attending clinician) to "rate total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his condition at admission to the project, how much has he changed?" (Guy, 1976, p. 218). The rater selects from the following numbered options: (0) not assessed, (1) very much improved, (2) much improved, (3) minimally improved, (4) no change, (5) minimally worse, (6) much worse, (7) very much worse. Generally, those classified as very much improved or much improved are considered responders.

The ABC-I (Aman & Singh, 1986) is comprised of the following 15 items: injures self, aggressive to other patients and staff, screams inappropriately, temper tantrums, irritable, yells at inappropriate times, depressed mood, demands must be met immediately, cries over minor annoyances and hurts, mood changes quickly, cries and screams inappropriately, stamps feet while banging objects or slamming doors, deliberately hurts self, does physical violence to self, and throws temper tantrums when he/she does not get own way. The rater indicates whether a particular item is not a problem at all (0), a slight problem (I), a moderate problem (2), or a severe problem (3). Thus, the maximum score is 45 and the minimum score is 0. The rater is asked to consider the experiences of others caring for the person and whether the behavior

interferes with development, functioning, or relationships. The rater is also asked to consider relative frequency. Specifically, the instructions state the following:

> Take relative *frequency* into account for each behavior specified. For example if the client averages more temper outbursts than most other clients you know or most others in his/her class, it is probably moderately serious (2) or severe (3) even if these occur only once or twice a week. Other behaviors, such as noncompliance, would probably have to occur more frequently to merit an extreme rating. (Aman & Singh, 1994, p.2)

The reliability and validity of the complete Aberrant Behavior Checklist (ABC) (comprised of 58 total items,15 of which make up the irritability subscale) are summarized in the ABC manual (Aman & Singh, 1986). With respect to reliability, the scale has high internal consistency and test-retest reliability. The authors report mean Spearman correlations to be equal to .63 (.55 for the irritability subscale). Criterion group validity was demonstrated by showing that those with higher scores (indicating more problematic behaviors) were less likely to attend training facilities (because of the difficulty of their behavior). In addition, the authors showed that those people with down syndrome scored lower on the subscales of irritability, stereotypic behaviors, and hyperactivity than those without down syndrome confirming similar findings of past researchers. Convergent and discriminant validity were demonstrated by comparing ABC scores with scores on several other scales. Finally, the scale was found to correlate with behavioral observations on all scales save the irritability scale. Low rates of behavior and large amounts of variability in the behaviors associated with the irritability subscale did not produce a statistically significant difference.

The aforementioned scales are most often used to evaluate the effect of a drug on problem behaviors. However, there a number studies where the frequency of a problem behavior

is described during a control and drug condition. In the case of contingent skin shock, behavior problem frequency is, almost exclusively, used to evaluate efficacy. Frequency data, of course, is a superior dependent variable because it is a direct measurement thereby eliminating observer bias and test validity (Lindsley, 1964). Johnston and Pennypacker (1980) provide a complete description of the advantages of frequency as a dependent variable.

Studies were included for analysis if ABC-I, CGI-I, or frequency data were reported. If multiple doses of a drug were used or several baseline or placebo conditions were present, the placebo condition with the highest ABC-I score and the drug condition with the lowest ABC-I score or was utilized for the comparison. In most cases, CGI-I and frequency data was readily accessible. However, in a few cases, CGI-I and frequency data was estimated from a graphic because raw data was not reported. Those studies that utilized time sampling were also included. However, partial interval time samples were converted to frequency by assuming that only one behavior occurred within each interval. For example, if 10 second samples were taken for 60 minutes and the behavior occurred in 50% of the intervals, the response was described as occurring 180 times per hour. To allow for comparisons, all frequency data was converted to frequency per day. A day was considered to be composed of 16 waking hours. Therefore, responses per minute, hour, day, week, month, and year were converted to responses per day by respectively multiplying each by 960, 16, 1, 1/7, 1/30, 1/365. For CSS data, the mean baseline frequency was the mean of all baseline data points. Generally, the last three reported data points or data describing the end result of the treatment were used to calculate the mean treatment frequency.

Efficacy of First Generation Drugs

First generation antipsychotic study selection. Studies describing the efficacy of FGA were obtained in two ways. First, all of the studies listed by Thompson, Hackenberg, and Schaal (1991) in Table D-1 (p.374-375) were obtained. In addition, all single subject design studies they cited within the section on neuroleptics were obtained. Second, PubMed and PsychINFO searches (limited to the period between 1990 and 2011) were performed with search terms such as "neuroleptic", "antipsychotic", "developmental disability", "autism", "intellectual disability", as well as the brand and generic names of FGA. Finally, the reference sections of obtained articles were examined.

Review methodology. To describe the efficacy of FGA in treating destructive behaviors the conclusions of a previous review are first summarized. Second, because only six relevant studies since 1990 were found, each is briefly reviewed. Finally, ABC-I, CGI-I, and frequency data derived from the previous review and six studies since 1990 are described.

1991 Conclusions. Thompson, Hackenberg, and Schaal (1991) summarized studies between 1971 and 1989 where FGA were used to treat destructive behaviors in people with developmental disabilities. After reviewing a series of studies related to chlorpromazine, they stated the following:

> In summary, the literature concerning the therapeutic effects of chlorpromazine on the problem behaviors of people with mental retardation suggests that, although in some cases some therapeutic benefit has been observed, in most cases it was either (1) not observed, (2) observed, but at the expense of adverse side effects, (3) observed, but perhaps not to a clinically-relevant degree, (4) observed, but inferior to behavioral treatments, or (5) observed, but inferior to other drug treatments. (p. 380)

Regarding thioridazine, the authors again noted the variability in efficacy and concluded the drug was likely more effective than chlorpromazine, especially in reducing stereotypical behavior. Regarding haloperidol, the authors concluded the findings from the literature suggested a range of efficacy from ineffective to highly effective. The authors concluded these drugs can result in beneficial effects in addressing certain behavior disorders. However, because of issues associated with measurement, heterogeneity of participant samples, and absence of functional diagnosis of behavior problems, they noted it was difficult to state which individuals with which behavior disorders were likely to benefit.

1990-2011 review. Since 1990, it appears that no further research has been conducted specifically on the efficacy of chlorpromazine as a treatment for destructive behaviors. However, there have been a few new research studies addressing the efficacy of other FGA.

Singh, Landrum, Ellis, and Donatelli (1993) found that thioridizine at 1.25 mg/kg was effective in reducing stereotypy (measured by percentage of 10 second intervals of occurrence) in three participants with mental retardation. Specifically, during baseline, the participants engaged in stereotypy in 84.3, 87.4, and 63.3% of intervals respectively. During the last 5 days of treatment with thioridazine, the percent of intervals with stereotypy decreased to 51.4, 61.6, and 32.4% respectively. Treatment with thioridazine was also associated with increases in social behavior. However, a response contingent 10 second visual screening was more effective than thioridazine in reducing stereotypy and resulted in higher percentages of intervals with appropriate social behavior.

May et al. (1995) described the effect of the gradual removal of thioridazine from 23 adults with developmental disabilities between 1989 and 1993. They found the participant could be classified into one of three groups. For 9 participants, problem behavior frequency increased

and subsequently decreased. For 5 participants, problem behavior frequency progressively decreased. For the remaining 9 participants, problem behavior frequency steadily increased. Seven of 9 who experienced regression continued to require psychotropic medication.

Mace, Blum, Sierp, Delaney, and Mauk (2001) contrasted the efficacy of haloperidol or placebo and behavior treatments based on function (e.g. extinction, differential reinforcement of alternative behavior, scheduled breaks) in treating self-injurious behaviors in 15 people with developmental disabilities. The functional analysis condition associated with the highest rate of self-injury served as the study baseline. Participants were randomly assigned to receive one of two treatments; haloperidol only or placebo plus behavioral treatment. If either treatment was unsuccessful in reducing self-injury by 75% or more, the other treatment was substituted. Two participants received haloperidol continuously (because of concerns about withdrawing the drug), 8 were assigned to haloperidol only, and 5 were assigned to placebo and behavior treatment. The haloperidol only intervention was successful in reducing self-injury in 2 of 8 participants by 98.9 and 100%. When behavioral procedures and placebo were substituted for haloperidol, the following percent reductions were observed: 100; 72.8; 11.4; 80.8; 90.3 (one participant dropped out before exposure to the behavioral procedure and placebo). All five participants assigned to receive behavioral treatment plus placebo achieved the following percent reductions in self-injury: 92.3; 98.7; 100; 100; 96.1. The two participants who received haloperidol continuously plus behavioral intervention experienced a 100% reduction. The researchers also contrasted scores on ABC at baseline and after haloperidol treatment. No significant differences were noted between any subscales.

Janowsky, Barnhill, Shetty, and Davis (2005), in a retrospective chart review spanning 1990 – 1997, described the experience of FGA dose reduction or discontinuation in 136 adults

with disabilities. Of the 136, 53 were withdrawn successfully; 18 were withdrawn but continued some non-antipsychotic medication; 31 continued on FGA or were switched to SGA; 34 people failed during a FGA reduction or discontinuation and required a resumption or increase of the reduced or discontinued drug.

Miral et al. (2008) found that haloperidol reduced scores on the ABC from 67.1 to a statistically significant 45.8 after 12 weeks of treatment. In addition, those exposed to haloperidol showed statistically significant improvement in 4 of 5 subscales of the Ritvo-Freeman Real Life Rating Scale (RF-RLRS), Clinical Global Impression Scales, and Turgay DSM-IV PDD Rating Scale (TDPDD). In a related study, Gencer et al. (2008) continued to follow the same participants for an additional 12 weeks, thus creating a 24 week evaluation period. All of the improvement in RF-RLRS and ABC scores reported by Miral et al. (2008) were absent after 16 weeks in those treated with haloperidol. At 24 weeks, haloperidol reduced scores on the ABC from a mean of 67.1 to a mean of 58.1 and reduced scores on the TDPDD from 77.6 to 66.2. Only the change in TDPDD scores were statistically significant.

Tyrer et al. (2008) randomly assigned 86 adults with developmental disabilities who exhibited aggressive behaviors to receive risperidone, haloperidol, or placebo. The bottom line finding was that there was that there was no difference between the groups as measured by several rating scales (MOAS, ABC, CGI).

ABC-I. Three studies employing FGA as an independent variable and the ABC-I as a dependent variable have been conducted. White and Aman (1985) used a double blind, placebo controlled, crossover design to examine the effect of pimozide on several dependent variables used to measure the behavior of 8 people with moderate to profound mental retardation. ABC-I scores during placebo and pimozide treatment were 24.2 and 18.93 respectively.

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Aman and White (1988) compared a low, high, and individualized doses of thioridazine with placebo in 10 people with mental retardation. ABC-I scores associated with low, high, individualized, and placebo were 4.15, 5.18, 4.51, and 4.85 respectively.

Aman, Teehan, White, Turbott, and Vaithianathan (1989) compared ABC-I scores of 20 mentally retarded people aged 12-35 years while receiving placebo, a low dose of haloperidol, or a high dose of haloperidol. ABC-I scores associated with placebo, low dose haloperidol, and high dose haloperidol were 7.02, 5.68, and 7.00 respectively. However, when the participants were divided according to degree of stereotypy, ABC-I scores for those with low stereotypy classifications were 3.17, 3.71, and 5.42 for the placebo, low and high dose conditions. The ABC-I scores of those with high stereotypy classifications were 12.81, 8.62, and 9.38 for the placebo, low, and high dose conditions.

In summary, three studies show the mean ABC-I change from baseline/placebo to the FGA drug condition was 3.39 (range .7-5.27). This information was derived by comparing the highest baseline/placebo ABC-I score with the lowest ABC-I score in any drug condition.

CGI-I. Perry et al. (1989) found that 33 of 59 participants with autism treated with haloperidol for 6 months were rated as much or very much improved on the CGI-I.

Frequency Data. Four studies, describing the individual effect of FGA on destructive behaviors of 13 individuals are summarized in Table 6. In total, the effect of FGA on 55 individual behaviors are summarized. Table 6 shows the converted frequency per day with placebo or the absence of a FGA, the converted frequency per day with the FGA, the percent increase or decrease, as well as the multiply or divide by factor.

In Table 7, the number of behaviors reduced by various percentages is presented. Table 7 shows that 6 of 55 behaviors were reduced by 90% or more; 11 of 55 by 50% or more; and that

22 of 55 behaviors continued to occur at the same rate or increased in frequency. Of the 6 behaviors reduced by 90%, 4 were reduced by 100%.

Table 8 shows the effect of FGA on the destructive behaviors of 161 people across 5 studies. Only one of nine behaviors showed a >25% reduction in destructive behaviors.

Efficacy of Second Generation Drugs

Second generation antipsychotic study selection. PubMed and PsychINFO searches were performed with search terms such as "neuroleptic", "antipsychotic", "developmental disability", "autism", "intellectual disability", as well as the brand and generic names of each second generation antipsychotic medication. Finally, the reference sections of obtained articles were examined. Studies were included for analysis if any of the following dependent variables were used: ABC-I; CGI-I; or problem behavior frequency.

Review methodology. ABC-I, CGI-I, and frequency data were extracted and tabulated. The effect of SGA on each dependent variable is summarized below.

ABC-I. The ABC-I scores are summarized in Table 9. ABC-I scores taken before the administration of drug or placebo are listed in the baseline column. The last ABC-I score obtained in each study is listed in the endpoint column. For those studies with a placebo control, the mean baseline score in the drug groups was 23.69 while the mean score at endpoint was 11.39. For the placebo group, the mean score at baseline was 24.09 and the mean score at endpoint was 18.64. Thus, in the drug groups, the mean change from baseline to endpoint was 12.3 points on the ABC-I. In the placebo groups, the mean change from baseline to endpoint was 5.75. If the placebo effect is subtracted from the drug effect, 6.55 ABC-I points separated the drug and placebo groups.

For those studies without a placebo, the mean baseline ABC-I scores was 20.93 and the mean score at endpoint was 12.15, a difference of 8.78 points.

CGI-I. For those studies with a control group, of a possible 427 people, 230 were rated as much or very much improved (53.9%) on the CGI-I. For placebo, 54 or 329 (16.4%) were rated as much or very much improved.

For those studies without a control group, 246 of 429 (57.3%) were rated as much or very much improved.

Frequency Data. Eight studies, describing the individual effect of SGA on destructive behaviors of 88 individuals are summarized in Table 10. In total, the effect of SGA on 136 individual behaviors is summarized. Table 10 shows the converted frequency per day with placebo or the absence of a SGA, the converted frequency per day with the SGA, the percent increase or decrease, as well as the multiply or divide by factor.

In Table 11, the number of behaviors reduced by various percentages is presented. Table 11 shows that 34 of 136 behaviors were reduced by 90% or more; 90 of 136 by 50% or more; and than 20 of 136 behaviors continued to occur at the same rate or increased in frequency. Of the 34 behaviors reduced by 90% or more, 23 were reduced by 100%.

Table 12 summarizes group designs describing behavior frequency. Two studies, describing the effect of SGA on 93 people across 11 behaviors are described. Table 12 shows that 8 of 11 behaviors were reduced by 59% or more.

Efficacy of Contingent Skin Shock

Contingent skin shock study selection. Studies were obtained from a database maintained at The Judge Rotenberg Center and summarized at

http://www.effectivetreatment.org/bibliography.html. Reference sections of obtained articles were also examined.

Review methodology. Frequency data were extracted and tabulated. The effect of CSS on problem behavior frequency is summarized below.

Frequency Data. Thirty-two studies, describing the individual effect of CSS on destructive behaviors of 114 individuals are summarized in Table 13. In total, the effect of CSS on 117 behaviors is summarized. Table 13 shows the converted frequency per day in the absence of a CSS, the converted frequency per day with CSS, the percent increase or decrease, as well as the multiply or divide by factor.

In Table 14, the number of behaviors reduced by various percentages is presented. Table 14 shows that 110 of 117 behaviors were reduced by 90% or more; 112 of 117 by 50% or more; and that 5 of 117 topographies continued to occur at the same rate or increased in frequency. Of the 110 topographies reduced by 90% more, 83 were reduced by 100%.

Frequency Comparisons across FGA, SGA, and CSS. The mean frequency of the behaviors treated with each CSS, FGA, and SGA are presented in Table 15. The table shows that those behaviors treated with CSS occurred at a far higher frequency than those treated with FGA or SGA. The table also shows that on the whole, CSS was far more effective in reducing destructive behavior than FGA or SGA.

Discussion

Comparison of Side Effects

Based upon the current review, the side effects associated with FGA and SGA are far greater in number, severity, and probability than those associated with CSS. Based upon the data reported by Ray et al. (2009), by giving 700 people between the ages of 30-74 a drug from either

class for a year, we can expect one of those 700 die as a result of the drug. Death can also result from NMS. Both groups of drugs are likely to cause obesity and sexual dysfunction. Obesity, of course, is associated with a host of health risks such as diabetes, heart disease, and cancer. Giving a person with a developmental disability a drug that interferes with appropriate sexual expression adversely affects their quality of life. Generally, SGA are only marginally safer than FGA when it comes to the development of TD. Finally, both FGA and SGA can cause the person taking them to either be somnolent, sedated, or generally tired. In the placebo controlled studies reported here, this effect was reported in 52% of those given an SGA compared to 13% given placebo. In studies without a placebo control, this effect was reported in 40% of those given SGA. Those with extremely dangerous or difficult behaviors are likely to be given high doses of FGA or SGA, further increasing the probability of sedation.

One advantage FGA and SGA appear to have over CSS is that they do not cause pain. However, the side effects, administration, and monitoring of these drugs can be painful. Dystonic reactions can be painful and distressing to person experiencing them (Dressler and Benecke, 2005; Marder & van Kammen, 2005). Drugs that are injected intramuscularly can cause acute pain. Venipuncture, necessary for monitoring adverse effects on the body caused by clozapine, also causes pain. Both intramuscular injections and venipuncture can cause panic, avoidance responses, and emotional behavior (Caprilli, Anastasi, Grotto, Scollo Abeti, & Messeri, 2007). The frequency with which these procedures are required is similar to the frequency skin shock is applied after the initial deceleration of the treated behavior.

Across all the studies reviewed, CSS was once associated with tiny pinpoint burns. However, the device in questions was not designed for human use. No other CSS device has ever been reported to cause tissue damage. The other negative side effects described include pain,

avoidance responses, and emotional reactions. When considering these side effects, it is important to consider the frequency of use. CSS is applied most frequently during first few days or weeks of treatment. Subsequently, the frequency of use most often continues to decelerate or drops to zero.

Compared to SGA and FGA, the side effects of CSS have not been evaluated in the same depth or with as many participants. However, because electricity has been applied to the body with therapeutic intensions for more than 100 years, there are well known sequelae of electrical stimulation (Bruner, 1994). These include muscular contraction, burns, seizures, and ventricular fibrillation and are described in detail by Bruner and Leonard (1989). CSS devices designed for humans are never placed over the major motor nerves, head, or chest and lack the power to cause burns, seizures, or ventricular fibrillation.

FGA, SGA, and CSS are often used over the long-term. Generally, CSS is used less often over time and therefore, any side effects should be expected to occur less frequently. However, sometimes, the intensity of the stimulus is increased to account for adaptation to a lower level stimulus. Conversely, many of the side effects of FGA and SGA are exacerbated with extended use. Specifically, the probability of TD increases approaching some maximum the longer one is exposed to the drug. In addition, SGA and FGA contribute to weight gain approaching some maximum the longer the drug is administered (Allison et al., 1999).

In summary, based upon the information presented here, the side effects associated with FGA and SGA appear to be more numerous and more severe when compared to those associated with CSS.

FGA Efficacy

The data summarized in this paper show that FGA are remarkably ineffective in treating destructive behaviors of people with developmental disabilities. The single subject frequency data clearly show that, for the 13 people across 55 topographies, FGA are not effective in reducing problem behaviors. These findings could be easily dismissed because of the low number of individuals examined. However, the group frequency data in Table 8 confirm the ineffective nature of these drugs in reducing destructive behaviors in 161 people with developmental disabilities. Clearly, there are some cases where the addition of an FGA was extremely effective. For example, in the Mace et al. (2001) report, the addition of haloperidol reduced self-injury by 99 and 100% in two individuals respectively. However, in the literature, these findings seem to be the exception rather than the rule. The ABC-I data, CGI-I data, and the remaining papers reviewed suggest that FGA are not effective in treating destructive behaviors.

SGA Efficacy

ABC-I. ABC-I scores in conditions with SGA were between 6.55 and 8.78 ABC-I points less than placebo or baseline conditions. In most cases, these changes were statistically significant. However, of what practical significance are these changes? In order to make such a determination, the properties of the ABC-I require examination.

One ABC-I point corresponds to a move from 3 to 2, 2 to 1, or 1 to 0 on one of 15 items between baseline and the endpoint measure (where 3 is severe problem, 2 is a moderate problem, 1 is a slight problem, and 0 is the absence of a problem). However, as described earlier, the ABC instructions advise the rater (typically a parent or primary care giver), using temper outbursts as an example, that behavior occurring more often than other class members, even only a few times per week could be rated as a severe problem. To describe severity, the rater also is asked to consider other clients in the class and other clients known by the rater. Thus, depending on the

experience of the rater, behavior may be rated as severe, even if the behavior occurred relatively infrequently and regardless of intensity. The diversity of the items in the ABC-I allow for a change of 8 points to represent extraordinary treatment outcomes or simple reductions in verbal disruption. For example, a move from a baseline score of 2 to an endpoint score of 0 on items describing aggression and self injury (items 2, 4, 50, 52) would represent an excellent outcome. On the other hand, a move from a baseline score of 2 to an endpoint score of 1 on items describing verbal disruption (items 8, 10, 14, 19, 29, 34, 36, 41), although beneficial, may obscure a lack of effect on items related to aggression and self-injury. The specificity described above could be interpreted as asking the ABC-I to do more than it was designed to be. However, unless a specific analysis is conducted to describe the effect of a particular drug on a particular item on the ABC-I, one cannot make conclusions about such effects.

In most cases, authors make concluding statements that reflect this problem. For example, Marcus et al. (2009) reported "...aripiprazole was effective at reducing irritability in children and adolescents with autistic disorder who also demonstrate irritability, agitation, self-injurious behavior, or a combination of these symptoms." (p. 1118). This statement reflects the fact that irritability is defined by the 15 items on the ABC-I. If the ABC-I scores decrease, one cannot say for certain that aggression, self-injury, yelling/screaming, or tantrums decreased. McCracken et al. (2002) reported "risperidone was safe and effective for the short-term treatment of tantrums, aggression, and self-injurious behavior in children with autistic disorder." (p. 319). Although it may be the case that all of these behaviors as measured by the ABC-I improved as the result of risperidone administration, without a separate analysis, such conclusions cannot be made.

Recently, Aman et al. (2010) described the effect of aripiprazole on individual items of the ABC-I. They found the most items were rated lower with aripiprazole when compared to placebo on the ABC-I scale with the exception of self-injury. More of these types of analyses would elucidate the effects of various SGA on individual behaviors. In addition, it would be helpful to see *post hoc* data that first classified participants as responders or non-responders, and second described the magnitude of the response. For example, one could report of *N* participants receiving the drug, *X* showed no change in ABC-I score. Of the remaining *Y* participants, the ABC-I scores decreased by *Z*. This would allow statements like the following: If this drug is given to *N* similar people, it will be effective to *Z* degree for *Y* of them.

CGI-I. The shortcomings of the CGI-I have been described (Beneke & Rasmus, 1992). The CGI data show that 53.9 to 57.3 percent of the participants receiving SGA are rated as much or very much improved on the CGI-I. Although clearly there are differential responses to the various drugs, this suggests that just over half of those treated get better as a result of treatment. However, to what degree to they get better? What does much or very much improved on the CGI-I mean? The validity of the CGI-I is largely derived from the requirement that a trained clinician makes the judgment of improvement or deterioration (Berk et al., 2008). The question is, then, what information does the clinician use to make their judgment? It would be interesting to determine if CGI-I ratings correlate with changes in behavior frequency or changes in the ABC-I. The CGI-I results are consistent with naturalistic results reported by Lemmon, Gregas, & Jeste (2011) who found that of 80 patients treated with risperidone at a clinic for destructive behaviors, 53% of them showed some improvement at 1 year.

Frequency data. The frequency data suggest that SGA are more effective than FGA in reducing destructive behaviors. The single subject data show that 23 of 136 behaviors (exhibited

by 88 different people) were completely eliminated by adding an SGA. In addition, 90 of the 136 behaviors were reduced by 50% or more. Data from the group studies showed that destructive behaviors were reduced by 59-78% for 8 of 11 behaviors. Whether this degree of reduction is sufficient depends on the nature of the behavior reduced. For example, if the behavior is sufficiently intense where the emission of only a few responses is likely to cause injury to the person or someone else, reducing a response by even 90% may not allow the person to enter the community or be free from restraint. In addition, for behavior occurring at high rates, a 50% reduction may be of little consequence. For example, if a destructive behavior is occurring 2000 times per day and reduced by 50% to 1000 times per day, we could expect little improvement in his or her living situation, quality of life, or access to the community. For a complete discussion of problems associated with employing percent increases and decreases, see Graf and Lindsley (2002).

CSS Efficacy

This review and analysis shows that CSS is by far the most effective procedure for reducing destructive behaviors. The single subject data show that 83 of 117 behaviors (exhibited by 114 different people) were completely eliminated by adding CSS. In addition, 110 of the 117 behaviors were reduced by 90% or more. However, it is important to point out that in order to be tolerable, CSS must work rapidly and maintain a low rate of problem behavior. For example, if a behavior occurs 20,000 times per day in the absence of treatment and is reduced by 98% by CSS, the person would be receiving 400 CSS applications per day; unlikely an acceptable result. Still, the results presented here suggest that indeed CSS is effective to such a degree that the destructive behavior is often completely eliminated.

The results are more remarkable when one considers that the behaviors treated with CSS are likely far more severe and certainly more frequent compared to the behaviors addressed in the medication studies. Specifically, mean daily rate of the behaviors treated with CSS summarized here was equal to 5300.23, nearly 19 times more frequent than those behaviors treated with SGA.

Limitations

There are numerous limitations associated with the overall analysis. First, by limiting the review to only studies where frequency, ABC-I, and CGI-I scores are reported, information is neglected. Dependent variables such as the Children's Psychiatric Rating Scale, Clinical Global Impressions – Severity, and many others were excluded from analysis. Second, studies reporting frequency were included even if weak experimental designs were utilized and/or in the absence of interobserver reliability. Third, to aid in comparison, all frequency data were represented as responses per day. In many cases, frequency data were derived from experimental conditions where a response was measured for a short experimental condition. In some cases, the condition may have transiently increased the frequency of the behavior by presenting stimuli known to evoke problem behaviors or by reinforcing such behaviors. Transient increases in frequency may also have been caused by removing accustomed mechanical restraint. People with developmental disabilities often learn to restore restraint through the emission of high frequency aggressive or self-injurious behaviors. Thus, in some cases, it is unlikely the response would have continued at the same rate throughout the entire day. Converting from responses per week or month to responses per day is much less problematic. Fourth, the CGI-I and ABC-I were never used to assess the effects of CSS which make cross comparison between interventions impossible. The main advantage of the CGI-I and ABC-I is that they are easy to use and require only a few

minutes to complete. Thus, they are much more appropriate for placeho controlled between group designs. Such designs have not been employed with CSS. Fifth, all individual FGA, SGA, and CSS interventions were grouped together with respect to side effects and efficacy. Clearly, side effects vary widely among the drugs. With regard to efficacy, the tables provided allow readers to extract data with respect to any compound of interest. Regarding CSS, the magnitude and type of the CSS application (duration, intensity, and wave form) are important factors that dictate efficacy and side effects and are not discussed here. Sixth, in many cases, concurrent treatments were involved. Many of the drug studies allowed the concurrent treatment with other classes of drugs and other antipsychotics in some cases. In addition, most CSS programs include, at the minimum, differential reinforcement. Finally, at least two studies (Aman, De Smedt, Derivan, Lyons, & Findling, 2002; and Israel et al., 2008) involved some people that emitted destructive behaviors but were not classified as having a developmental disability.

The treatment of a person with destructive behaviors often involves many components including non-antipsychotic medication, a range of behavioral procedures, as well as other treatments. One might argue that medication is simply part of an overall treatment package that is usually successful and that CSS in therefore unnecessary. Aman et al. (2009), for example, demonstrated that risperidone or aripiprazole combined with simple parent training was more effective than drugs alone. Future research should be devoted to examine such interaction effects.

One may criticize the long-term use of CSS citing that the effects sometimes are only maintained as long as the contingency remains. Indeed, CSS sometimes loses efficacy due to adaptation, inconsistent use (e.g. Williams, Kirkpatrick-Sanchez, & Iwata, 1993), or the destructive behaviors return after CSS is removed (e.g. Israel et al., 2010; student #3). It should

be noted that there are many examples where CSS is withdrawn and destructive behaviors remain absent (e.g. Foxx, Bittle, & Faw, 1989; Salvy, Mulick, Butter, Bartlett, & Linscheid, 2004 among others). In addition, FGA and SGA also are only effective as long as the person continues to take them and the risk and severity of many side effects increase over time. Finally, even the temporary elimination of behaviors otherwise intractable to other interventions that require frequent restraint, inhibit skill acquisition or education, prevent entry into the community, or cause a person to live away from their family should be considered a success.

Conclusions

The decision making model described by Mikklson (2007) asks one to consider the following three factors when examining treatment options: severity of symptoms, the probability the treatment will be successful, and the side effect profile of the treatment. Regarding symptom severity, the analysis presented here suggests that the behaviors treated with CSS in the literature are certainly more frequent than those treated with FGA or SGA. It is also likely the behaviors treated with CSS were generally more severe in degree. Regarding the probability of treatment success, the analysis presented here suggests that CSS is by far the most effective procedure to address destructive behaviors, followed by SGA, and FGA. Finally, the negative side effects associated with SGA and FGA seem to be more probable and numerous than those associated with CSS. On the other hand, the positive side effects associated with CSS seem to more probable and numerous than those associated with SGA and FGA.

Unfortunately, due to the ineffective nature of the procedures currently employed, the search for new procedures leads to interventions such as Electroconvulsive Therapy (Wachtel et al., 2009), psychosurgery (Fountas, Smith, & Lee, 2007), or the continued use of dangerous restraint procedures. As procedures based upon behavior function and differential reinforcement

continue to be refined, perhaps the need for interventions like CSS will decline. However, it is clear that our current technology is not able to treat all destructive behavior emitted by people with developmental disabilities. Perhaps consideration could be given to conducting research and developing treatment delivery systems to make use of procedures known to be extremely effective for intractable destructive behaviors. The information obtained could be used to inform families with members who exhibit intractable destructive behaviors, lawmakers, and the general public.

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Table 1

Placebo Controlled Studies Side Effect Summary

	Drug			Placebo		
Side Effect	**Frequency**	***N***	**%**	**Frequency**	***N***	**%**
Abdominal Pain	19	244	8	4	128	3
Abnormal Gate	1	15	7	0	16	0
Aggression	1	47	2	4	50	8
Aggressive reaction	1	39	3	4	38	11
Agitation	2	15	13	5	16	31
Akathisia	0	47	0	1	50	2
Anorexia	7	67	10	2	67	3
Anxiety	12	49	24	10	51	20
Apathy	5	40	13	0	39	0
Constipation	23	110	21	7	111	6
Coughing	22	232	9	9	118	8
Decreased Appetite	17	220	8	6	107	6
Diarrhea	14	111	13	16	117	14
Dizziness	8	49	16	2	51	4
Drooling	32	261	12	3	152	2
Drowsiness	24	49	49	6	51	12
Dry Mouth	10	64	16	5	67	7
Dyskinesia	7	76	9	3	51	6
Dyspepsia	9	70	13	4	79	5
Earache	2	49	4	4	51	8
Elevated serum prolactin	7	55	13	1	63	2
Enuresis	24	276	9	20	168	12
Epistaxis	5	165	3	0	51	0
Extrapyramidal Disorder	14	239	6	0	101	0
Fatigue	68	301	23	23	254	9
Fever	15	67	22	12	67	18
Gastroenteritis viral	5	165	3	0	51	0
Glazed Eyes	1	6	17	0	5	0
Headache	52	401	13	31	297	10
Hyperkinesia	2	74	3	1	50	2
Hypersomnia	5	165	3	0	51	0
Hypokinesia	2	74	3	0	50	0
Increased Thirst	11	220	5	7	107	7
Influenza-like symptoms	7	67	10	3	67	4
Injury	7	39	18	5	38	13
Insomnia	21	181	12	27	183	15
Inv, Muscle contraction	1	27	4	1	28	4
Lethargy	10	165	6	0	51	0
Muscle Rigidity	6	96	6	1	101	1
Muscle Spasms	0	47	0	1	50	2
Nasal Congestion	34	261	13	22	152	14

Nasopharyngitis	18	212	8	5	101	5
Nausea	12	214	6	6	102	6
Nervousness	0	6	0	1	5	20
Psychomotor hyperactivity	1	47	2	2	50	4
Pyrexia	19	212	9	1	101	1
Rash	4	165	2	1	51	2
Restlessness	3	49	6	3	51	6
Rhinitis	19	128	15	9	135	7
Rhinorrhea	8	165	5	1	51	2
Saliva Increased	19	232	8	3	118	3
Sedation	57	233	24	5	122	4
Siolorrhea	1	15	7	0	16	0
Skin Irritation	11	49	22	7	51	14
Sleep Problems	11	49	22	9	51	18
Somnolence	108	373	29	21	269	8
Sore Throat	5	49	10	1	51	2
Stomachache	5	49	10	9	51	18
Tachydardia	11	89	12	1	90	1
Tardive Dyskenisia	0	27	0	1	28	4
Tremor	34	328	10	1	191	1
Upper Respiratory Tract Inf.	37	328	11	18	219	8
Vomiting	65	383	17	34	282	12

Table 2

Combined Sedation, Somnolence, Drowsiness, and Lethargy Side Effects from Placebo Controlled Studies

		Drug		Placebo	
Study	**Side Effect Label**	**Frequency**	***N***	**Frequency**	***N***
McDougle (1998)	Sedation	9	15	0	16
Aman (2002)	Somnolence	28	55	6	63
McCracken (2002)	Drowsiness	24	49	6	51
	Fatigue	29		14	
Shea (2004)	Fatigue	4	40	1	39
	Somnolence	29		3	
Gagiano (2005)	Somnolence	9	39	6	38
Hollander (2006)	Sedation	4	6	1	5
Pandina (2007)	Somnolence	20	27	2	28
Owen (2009)	Fatigue	10	47	2	50
	Sedation	5		1	
	Somnolence	8		2	
Marcus (2009)	Fatigue	25	165	0	51
	Lethargy	10		0	
	Sedation	39		3	
Totals		**253**	**483**	**43**	**341**

Table 3

Non-placebo Controlled Studies Side Effect Summary

Side Effect	Frequency	*N*	%	Side Effect	Frequency	*N*	%
Abdominal Pain	6	49	12	Increased Thirst	8	35	23
Abnormal EKG	2	62	3	Inflicted injury	7	58	12
Abnormal Gate	1	20	5	Injury	15	58	26
Abnormal Hepatic fx	10	62	16	Insomnia	47	225	21
Abnormal lipid profile	10	62	16	Irritability	3	26	12
Aggression	2	9	22	Knee pain	1	25	4
Aggressive reaction	11	58	19	Lethargy	3	33	9
Agitation	28	194	14	Leukopenia	1	6	17
Akathisia	8	141	6	Lip Biting	1	25	4
Anxiety	27	100	27	Listlessness	1	17	6
Apathy	6	58	10	Mouth Opening	1	54	2
Asthenia	15	37	41	Muscle Rigidity	2	34	6
Behavioral Activation	1	6	17	Nasal Congestion	9	83	11
Blood in Stool	1	25	4	Nausea	25	181	14
Blunted Affect	1	18	6	Nausea/vomiting	12	50	24
Cataplexy	1	6	17	Neck Stiffness	1	25	4
Constipation	35	145	24	Nervousness	6	25	24
Coughing	51	74	69	Ocul. dystonia	6	54	11
Cutaneous Rash	1	20	5	Oral dyskinesia	1	12	8
Decreased Appetite	11	123	9	Pain in extremities	1	13	8
Decreased Urination	1	25	4	Pedal edema	1	8	13
Diarrhea	38	165	23	Pharyngitis	9	49	18
Dizziness	7	142	5	Polydipsia	11	49	22
Drooling	4	49	8	Polyuria	3	49	6
Drowsiness	14	18	78	Polyuria/polydipsia	6	33	18
Dry Mouth	27	101	27	Protruding tongue	1	23	4
Dyskinesia	7	49	14	Pseudoparkinsonism	4	33	12
Dyskinetic Mov.	2	54	4	Pyrexia	8	49	16
Dyspepsia	17	74	23	Rash	16	74	22
Dystonia	4	89	4	Rhinitis	23	109	21
Dysuria	2	25	8	Rhinorrhea	39	49	80
Ear Infection	2	49	4	Rigidity or Tremor	5	54	9
Ejacuation Dysfx	1	12	8	Saliva Increased	22	76	29
Elevated prolactin	44	57	77	Sedation	108	457	24
Emo. Lability/Agg	6	17	35	Sedation/GI complaints	13	40	33
Enuresis	38	256	15	Seizure	5	97	5
Epilepsy	1	7	14	Sinusitis	1	25	4
Epistaxis	7	49	14	Siolorrhea	13	100	13
Exacerbation of pain	1	20	5	Somnolence	48	107	45
EPS	2	62	3	Stomachache	3	26	12
Fatigue	51	133	38	Sweats	1	9	11
Fever	1	25	4	Tachydardia	9	126	7
Galactorrhoea	1	54	2	Tardive Dyskinesia	1	20	5
Gross Motor Incoord.	1	18	6	Tearfulness	1	25	4
Headache	42	233	18	Tics	1	9	11

Hematuria	1	25	4	Tinnitus	1	25	4
Hyperglicemia	1	62	2	Tiredness	15	25	60
Hyperphagia	11	23	48	Transient Lisping	1	12	8
Hyperprolactinemia	52	62	84	Tremor	14	189	7
Hypertension	1	6	17	Trouble Falling Asleep	2	25	8
Increased Activity	1	22	5	Trouble Waking Up	8	25	32
↑ liver enzymes	1	53	2	Vomiting	32	127	25
↑ motor activity	3	52	6	Weight Loss	6	12	50

Table 4

Combined Sedation, Somnolence, Drowsiness, and Lethargy Side Effects from Non-placebo Controlled Studies

Study	Side Effect Label	Frequency	*N*	%
McDougle (1997)	Sedation	6	18	33
Martin (1999)	Sedation	3	6	50
Friedlander (2001)	Sedation	10	54	19
Malone (2001)	Drowsiness	5	6	83
Masi (2001)	Sedation	1	24	4
Kemner (2002)	Sedation	6	25	24
	Asthenia	14		56
Malone (2002)	Sedation	15	22	68
McDougle (2002)	Sedation	5	12	42
Masi (2003)	Sedation	3	53	6
Gagliano (2004)	Sedation	6	20	30
Stravrakaki (2004)	Sedation	4	7	57
Stigler (2004)	Sedation	2	5	40
Findling (2004)	Sedation	7	9	78
Corson (2004)	Sedation	2	20	10
Harden (2005)	Sedation	3	10	30
Rugino (2005)	Listlessness	1	17	6
Gagiano (2005)	Fatigue	9	58	16
	Somnolence	24		50
Malone (2007)	Asthenia	1	12	8
	Drowsiness	9		75
Capone (2008)	Sedation	1	23	4
Stigler (2009)	Tiredness	15	25	60
	Trouble Waking Up	8		32
Amore (2011)	Sedation	12	62	19
Aman (2009)	Somnolence	24	49	49
	Fatigue	33		67
Hellings (2006)	Sedation/GI Complaints	13	40	33
Zarcone (2001)	Sedation	10	20	50
Troost (2005)	Fatigue	9	26	35
Cohen (1994)	Sedation	4	6	67
Janowsky (2003)	Sedation	4	20	20
Lott (1996)	Lethargy	3	33	9
	Sedation	1		3
Cohen (1998)	Sedation	3	8	38
Total		**276**	**690**	**40**

Table 5

Positive Side Effects of CSS Reported Since 1989

Study	Participant	Positive Behavioral Side Effects
Linscheid (1990)	Marie	Reductions in other problem behaviors (bites, hair pulls, hits to chair).
	Johnny	Increases in behaviors suggestive of relaxation and decreased distressed vocalizations.
	Donna	General improvement in adaptive functioning.
	Michael	Began attending to physical environment, more responsive to positive reinforcement, followed simple instructions, improved self-help skills.
	Diane	Improved response to instruction, improved waiting skills, improved general social interaction.
Ricketts (1992)		Higher rates of smiling and happy vocalizations and lower rates of distressed vocalizations when CSS was present. (the addition of naltrexone caused distressed vocalization to increase in the presence of CSS)
Williams (1993)		Regained total independence in self-feeding and improvement in other self-care skills, remission of selective mutism.
Linscheid (1994)		Increases in laughing, smiling, uttering a word associated with happiness, self-initiated toy play.
Mudford (1995)		"Richard appeared to prefer wearing the TSD, approaching any person who carried the equipment into his ward, and assisting in attaching it to himself. He never attempted to remove the device. Removal of the device provoked tantrum behaviors. He was judged by staff to be happier, calmer, and less clingy to people when wearing the TSD." (p. 264)
Linscheid (2002)		Increase in smiles, laughs, self-initiated communication, self-initiated socialization, decrease in pinching.
Salvy (2004)		Less distressed when upset, more responsive to reinforcement, emission of more appropriate behaviors.
van Oorsouw (2008)		Improvement or no change in the following behaviors: positive verbal and nonverbal utterances (smiling, dancing, singing, talking); negative verbal and nonverbal utterances (crying, whining, spitting, stamping feet etc); socially appropriate behavior (raising hand, greeting others, asking for help); off task behavior (head down on table refusing academic tasks).
Israel (2010)		Anecdotal reports of more family contact, skill acquisition, improved mood/outlook, and requests to have CSS added to behavioral program.

Table 6

Converted Frequency Data From First Generation Single Subject Design Studies

Study	Drug	Behavior	Identifying Label From Original Study	Baseline Converted Frequency Per Day	Drug Converted Frequency Per Day	Percent Increase or Decrease	Multiply/ Divide By Factor
Millichamp (1987)	Methotrimeprazine	Object stereotypy	Hugh	748.80	3070.08	↑ 310.00	x 4.1
	Methotrimeprazine	Body stereotypy		5374.08	3663.36	31.83	1.47
	Methotrimeprazine	Aggressive/destructive		5.76	270.72	↑ 4600.00	x 47
	Methotrimeprazine	Vocal sound		1054.08	1100.16	↑ 4.37	0.96
	Methotrimeprazine	Pica		5.76	5.76	0.00	1.00
	Methotrimeprazine	Self injury		0.00	5.76	↑ 476.00	x 5.76
	Methotrimeprazine	Object stereotypy	Richard	1296.00	950.40	26.67	1.36
	Methotrimeprazine	Body stereotypy		2672.64	1353.60	49.35	1.97
	Methotrimeprazine	Aggressive/destructive		11.52	11.52	0.00	1.00
	Methotrimeprazine	Vocal sound		1906.56	2217.60	↑ 16.31	0.86
	Methotrimeprazine	Pica		783.36	489.60	37.50	1.60
	Methotrimeprazine	Self injury		288.00	5.76	98.00	50.00
	Methotrimeprazine	Object stereotypy	Craig	362.88	5.76	98.41	63.00
	Methotrimeprazine	Body stereotypy		4527.36	5621.76	↑ 24.17	x 1.24
	Methotrimeprazine	Aggressive/destructive		0.00	0.00	0.00	0.00
	Methotrimeprazine	Vocal sound		783.36	86.40	88.97	9.07
	Methotrimeprazine	Pica		0.00	5.76	↑ 476.00	x 5.76
	Methotrimeprazine	Self injury		109.44	0.00	100.00	109.44
	Methotrimeprazine	Object stereotypy	Ian	3674.88	2275.20	38.09	1.62
	Methotrimeprazine	Body stereotypy		3669.12	2926.08	20.25	1.25
	Methotrimeprazine	Aggressive/destructive		0.00	0.00	0.00	0.00
	Methotrimeprazine	Vocal sound		276.48	161.28	41.67	1.71
	Methotrimeprazine	Pica		282.24	345.60	↑ 22.45	x 1.22
	Methotrimeprazine	Self injury		0.00	0.00	0.00	0.00
	Chlorpromazine	Object stereotypy	Dennis	3888.00	3317.76	14.67	1.17
	Chlorpromazine	Body stereotypy		5443.20	5656.32	↑ 3.92	x 1.04

	Chlorpromazine	Aggressive/destructive		0.00	0.00	0.00	0.00
	Chlorpromazine	Vocal sound		374.40	305.28	18.46	1.23
	Chlorpromazine	Pica		5.76	0.00	100.00	5.76
	Chlorpromazine	Self injury		17.28	17.28	0.00	1.00
	Chlorpromazine	Object stereotypy	Kevin	604.80	529. 92	12.38	1.14
	Chlorpromazine	Body stereotypy		4838.40	4970.88	↑ 2.74	x 1.03
	Chlorpromazine	Aggressive/destructive		0.00	0.00	0.00	0.00
	Chlorpromazine	Vocal sound		97.92	0.00	100.00	97.92
	Chlorpromazine	Pica		0.00	0.00	0.00	0.00
	Chlorpromazine	Self injury		5.76	0.00	100.00	5.76
Burgio (1985)	Thioridazine	Aggression (play)	Doug	768.00	307.20	60.00	2.50
	Thioridazine	Disruption (play)		307.20	230.40	25.00	1.33
	Thioridazine	Self Stim (play)		3939.84	2995.20	23.98	1.32
	Thioridazine	Mouthing (play)		4147.20	3609.60	12.96	1.15
	Thioridazine	Aggression (academic)		76.80	23.04	70.00	3.33
	Thioridazine	Disruption (academic)		281.86	153.60	45.50	1.84
	Thioridazine	Self Stim (academic)		3018.24	1612.80	46.56	1.87
	Thioridazine	Mouthing (academic)		3532.80	2764.80	21.74	1.28
	Thioridazine	Aggression (play)	Terry	215.04	691.20	↑ 221.43	x 3.21
	Thioridazine	Disruption (play)		944.64	3609.60	↑ 282.11	x 3.82
	Thioridazine	Self Stim (play)		5015.04	6528.00	30.17	x 1.3
	Thioridazine	Aggression (academic)		7.68	2.30	70.00	3.33
	Thioridazine	Disruption (academic)		230.40	691.20	↑ 200.00	x 3
	Thioridazine	Self Stim (academic)		3632.64	3609.60	0.63	1.01
Luiselli (1986)	Haloperidol	Face striking	Anne	1248	1824	↑ 46.15	x 1.46
	Thioridazine	Self injury	Frank	248	377	↑ 52.02	x 1.52
Singh (1993)	Thioridazine	Stereotypy	Subject 1	4856.68	2776.32	42.84	1.75
	Thioridazine	Stereotypy	Subject 2	5034.24	3548.16	29.52	1.42
	Thioridazine	Stereotypy	Subject 3	3646.08	1866.24	48.82	1.95

Table 7

Behaviors Treated with First Generation Antipsychotic Medication Classified According to Percent Reduction

Percent Reduction	Number of Behaviors	Percent of Sample
90	6 [a]	10.9
80	1	1.8
70	2	3.6
60	1	1.8
50	1	1.8
40	7	12.7
30	4	7.3
20	6	10.9
10	4	7.3
.01	1	1.8
No change or Increase	22	40

[a] 4 behaviors were reduced by 100%

Table 8

Converted Frequency Data From First Generation Group Design Studies

Study	Drug	Behavior	*N*	Baseline Converted Mean Frequency Per Day	Drug Converted Mean Frequency Per Day	Percent Increase or Decrease	Multiply/ Divide By Factor
Heistad (1982)	Thioridazine	Self stimulatory Behavior	100	5193.60	4387.20	15.53	1.18
		Active Negative - Pacing, injury to self, misappropriate, objectionable behavior, humiliate, tease, command negative, physical negative, yell, disapproval, and destructiveness.		988.80	816.00	17.48	1.21
		Passive negative - Inactivity, error, vanish from assigned place, whine, cry, dependency, noncompliance, ignore.		1065.60	1046.40	1.80	1.02
Aman (1988)	Thioridazine	Self stimulatory beh. including self-injury	10	1884.00	1416.00	24.84	1.33
	Thioridazine	Any rule violation		199.00	80.00	59.80	2.49
Aman (1989)	Haloperidol	Self stimulatory beh. including self-injury	20	1381.00	1450.00	↑5.00	x 1.05
	Haloperidol	Any rule violation		285.00	231.00	18.95	1.23
May (1995)	Thioridazine	Destructive Behaviors	23	746.00	882.00	↑18.23	x 1.18
Mace (2001)[a]	Haloperidol	Self injury	8	2000	1580.80	20.96	1.27

[a] In this study, the effect of the presence and absence of haloperidol was compared with the presence and absence of placebo. The baseline converted mean per day was 2342.4 the placebo converted mean per day was 2969.6; and the percent increase was equal to 21.

Table 9

ABC-I and CGI-I Scores From Studies Examining Second Generation Antipsychotic Efficacy

					ABC-I				CGI-I	
					Drug		Placebo			
Study	**Drug**	**N**	**Participants**	**Age**	**Baseline**	**Endpoint**	**Baseline**	**Endpoint**	**Drug**	**Placebo**
Perry (1997)	Risperidone	6	PDD	7-14	-	-	-	-	4/6	-
McDougle (1997)	Risperidone	18	PDD	5-18	-	-	-	-	12/18	-
McDougle (1998)	Risperidone	31	Autism PDD	18-43	-	-	-	-	8/14	0/16
Nicolson (1998)	Risperidone	10	Autism	4 -10	-	-	-	-	8/10	-
Martin (1999)	Quetiapine	6	Autism	6-15	15.67	22.3	-	-	2/6	-
Friedlander (2001)	Risperidone	40	DD	13-24	-	-	-	-	23/40	-
Malone (2001)	Olanzapine	6	Autism	4-12	-	-	-	-	5/6	-
Masi (2001)	Risperidone	24	Autism	3-6	-	-	-	-	8/22	-
Zarcone (2001)	Risperidone	20	Autism; DD	6-65	17.9	10.6	-	-	-	-
Aman (2002)	Risperidone	118	IQ 36-84	5-12	23.5	13.5	23.6	19.2	28/52	5/63
McCracken (2002)	Risperidone	101	Autism	5-17	26.2	11.3	25.5	21.9	38/49	6/52
Kemner (2002)	Olanzapine	23	Autism	6-16	11.1	8.1	-	-	3/23	-
Malone (2002)	Risperidone	22	Autism	2-16	-	-	-	-	17/22	-
McDougle (2002)	Ziprasidone	10	Autism; PDD	8-20	-	-	-	-	6/12	-
Masi (2003)	Risperidone	47	Autism; PDD	3-6	-	-	-	-	22/47	-
Shea (2004)	Risperidone	79	Autism	5-12	18.9	6.8	21.2	14.7	21/40	7/38
Galiano (2004)	Risperidone	20	Autism	3-10	-	-	-	-	8/20	-
Stravrakaki (2004)	Olanzapine	7	Autism; PDD	8-52	-	-	-	-	6/7	-
Stigler (2004)	Aripiprizole	5	PDD-NOS	5-18	-	-	-	-	5/5	-
Findling (2004)	Quetiapine	9	Autism	10-17	19	9	-	-	2/9	-
Corson (2004)	Quetiapine	20	Autism; PDD	5-28	-	-	-	-	8/20	-
Harden (2005)	Quetiapine	10	Autism PDD	5-19	-	-	-	-	6/10	-
Rugino (2005)	Risperidone	7	Autism; PDD	5-17	-	-	-	-	2/7	-
Gagiano (2005)	Risperidone		Adults with MR	18-65	18.4	8	17.9	12.1	-	-
					31.2	22.2	-	-	-	-

Troost (2005)	Risperidone	36	Autism	5-17	23.1	12	-	-	-	-
Hellings (2006)	Risperidone	40	DD	5-56	19.15	11.15	-	-	-	-
Hollander (2006)	Olanzapine	11	Autism PDD	6-14	-	-	-	-	3/6	1/5
Malone (2007)	Ziprasidone	12	Autism	12-18	1.5	1.1	-	-	9/12	-
Pandina (2007)	Risperidone	55	Autism	5-12	20.6	7.2	21.6	14.1	14/27	6/28
Fido (2008)	Olanzapine	40	Autism	7-17	20	6.2	-	-	12/40	-
Tyrer (2008)	Risperidone	86	Adults with MR	28-55	-	-	-	-	7/29	5/29
Capone (2008)	Risperidone	23	Autism; DD	3-13	15.8	10.7	-	-	-	-
Aman (2009)	Risperidone[a]	47	Autism; PDD	4-13	29.69	14.53	-	-	-	-
Stigler (2009)	Aripiprizole	25	PDD-NOS	5-17	29.6	8.1	-	-	22/25	-
Marcus (2009)	Aripiprizole	213	Autism	6-17	28.6	16.2	28	19.6	87/164	17/49
					28.2	15	-	-	-	-
					28.9	14.5	-	-	-	-
Owen (2009)	Aripiprizole	98	Autism	6-17	29.6	16.7	30.8	26.8	24/46	7/49
Amore (2011)	Risperidone	31	MR	-	-	-	-	-	29/31	-
	Olanzapine	31	MR	-	-	-	-	-	21/31	-
Marcus (2011)	Aripiprizole	48[b]	Autism	6-17	23.1	16.7	-	-	-	-

[a]Participants were switched to aripiprazole if risperidone was ineffective.
[b]Participants selected from de novo group only.

Table 10

Converted Frequency Data From Second Generation Single Subject Design Studies

Study	Drug	Behavior	Identifying Label From Original Study	Baseline Converted Frequency Per Day	Drug Converted Frequency Per Day	Percent Increase or Decrease	Multiply/ Divide By Factor
Cohen (1994)	Clozapine and Valproic Acid	Episodes of Agitation	Case 1	15.50	4.10	74	3.8
	Clozapine	Aggression	Case 2	0.60	0.17	72	3.6
	Clozapine	Self -injury	Case 2	1.37	0.47	66	2.9
	Clozapine	Verbal Aggression	Case 3	1.23	0.57	54	2.2
	Clozapine	Physical Aggression	Case 3	0.53	0.50	6	1.1
	Clozapine and Valproic Acid	Self -injury	Case 4	1.73	0.77	56	2.3
	Clozapine and Valproic Acid	Tantrums	Case 4	2.27	1.03	54	2.2
	Clozapine	Aggression	Case 5	0.40	0.00	100	12.0
	Clozapine and Valproic Acid	Aggression	Case 6	0.77	0.00	100	23.0
Lott (1996)	Risperidone	Aggression	1	0.08	0.28	↑240	x 3.5
	Risperidone	Self-injury	2	0.07	0.35	↑425	x 5.0
	Risperidone	Aggression	3	3.38	2.60	23	1.3
	Risperidone	Aggression	4	2.14	0.48	77	4.4
	Risperidone	Self-injury	4	10.20	3.76	63	2.7
	Risperidone	Self-injury	5	0.05	0.08	↑67	x 1.6
	Risperidone	Self-injury	6	0.01	0.10	↑850	x 10.0
	Risperidone	Aggression	7	2.24	0.31	86	7.1
	Risperidone	Self-injury	7	0.25	0.19	22	1.3
	Risperidone	Self-injury	8	0.02	0.00	100	0.02
	Risperidone	Aggression	9	25.12	11.74	53	2.1
	Risperidone	Self-injury	9	0.25	0.07	73	3.8
	Risperidone	Destruction	9	0.43	0.19	57	2.3
	Risperidone	Self-injury	10	4.89	1.16	76	4.2
	Risperidone	Aggression	11	0.12	0.02	81	5.3
	Risperidone	Aggression	12	0.03	0.01	60	2.5
	Risperidone	Self-injury	12	1.05	0.15	86	7.1
	Risperidone	Destruction	12	0.03	0.08	↑200	x 2.7
	Risperidone	Aggression	13	0.55	0.04	93	14.3
	Risperidone	Self-injury	13	1.38	0.02	98	62.8
	Risperidone	Self-injury	14	0.24	0.43	↑84	0.5

	Risperidone	Aggression	15	1.40	0.38	73	3.7
	Risperidone	Self-injury	16	0.35	0.28	19	1.2
	Risperidone	Aggression	17	0.55	1.38	↑151	x 2.5
	Risperidone	Self-injury	18	1.19	0.84	30	1.4
	Risperidone	Aggression	19	2.12	0.76	64	2.8
	Risperidone	Self-injury	19	3.76	2.41	36	1.7
	Risperidone	Aggression	20	0.08	0.02	71	3.5
	Risperidone	Aggression	21	0.08	0.80	↑873	x 10.0
	Risperidone	Self-injury	21	0.23	3.47	↑1405	x 15.1
	Risperidone	Destruction	21	0.02	0.00	100	0.02
	Risperidone	Self-injury	22	3.63	1.15	68	3.1
	Risperidone	Destruction	22	0.30	0.03	89	9.2
	Risperidone	Aggression	23	2.95	1.87	36	1.6
	Risperidone	Self-injury	23	0.59	0.31	47	1.9
	Risperidone	Aggression	24	0.03	0.00	100	0.03
	Risperidone	Self-injury	24	0.87	0.10	88	8.4
	Risperidone	Destruction	24	0.29	0.13	57	2.3
	Risperidone	Self-injury	25	0.80	0.13	84	6.0
	Risperidone	Aggression	26	0.31	0.20	36	1.6
	Risperidone	Self-injury	26	0.27	0.31	↑14	1.2
	Risperidone	Aggression	27	0.10	0.00	100	0.1
	Risperidone	Aggression	28	3.31	0.32	90	10.2
	Risperidone	Self-injury	28	0.91	0.17	81	5.4
	Risperidone	Aggression	29	1.22	0.04	96	27.8
	Risperidone	Aggression	30	0.09	0.03	69	3.2
	Risperidone	Self-injury	30	0.37	0.16	57	2.3
	Risperidone	Aggression	31	0.41	0.24	42	1.7
	Risperidone	Self-injury	31	0.75	0.56	26	1.3
	Risperidone	Aggression	32	0.57	0.37	35	1.5
	Risperidone	Self-injury	32	0.29	0.30	4	x 1.0
	Risperidone	Destruction	32	0.34	0.51	↑51	x 1.5
Cohen (1998)	Risperidone	Assault	1	0.01	0.00	100	0.01
	Risperidone	Self-injury	1	0.66	0.13	80	4.9
	Risperidone	Assault	2	2.57	0.13	95	19.3
	Risperidone	Disruption	2	2.53	0.03	99	76.0
	Risperidone	Assault	3	0.19	0.10	47	1.9
	Risperidone	Self-injury	3	0.36	0.30	16	1.2
	Risperidone	Assault	4	2.37	0.37	85	6.5
	Risperidone	Self-injury	4	16.64	3.87	77	4.3
	Risperidone	Assault	5	2.30	3.30	↑44	x 0.7

	Risperidone	Self-injury	6	2.09	0.00	100	2.1
	Risperidone	Assault	7	40.04	7.40	82	5.4
	Risperidone	Property Destruction	7	0.47	0.27	43	1.8
	Risperidone	Assault	8	0.06	0.00	100	0.06
	Risperidone	Self-injury	8	2.27	0.70	69	3.2
Cohen (1998)	Risperidone	Assault	1	0.01	0.00	100	0.01
	Risperidone	Self-injury	1	0.66	0.13	80	4.9
	Risperidone	Assault	2	2.57	0.13	95	19.3
	Risperidone	Disruption	2	2.53	0.03	99	76.0
Dartnall (1999)	Risperidone	Self-injury	1	1.22	0.00	100	1.2
	Risperidone	Aggression toward en.	1	0.23	0.00	100	0.2
	Risperidone	Noncompliance	2	1.40	0.00	100	1.4
	Risperidone	Hiding	2	0.47	0.01	98	42.7
	Risperidone	Assault	3	0.19	0.10	47	1.9
Crosland (2003)	Risperidone	Demand Destructive	Reggie	672.00	201.60	70	3.3
	Risperidone	Tangible Destructive	Reggie	1920.00	979.20	49	2.0
	Risperidone	Attention Destructive	Sean	14592.00	5664.00	61	2.6
	Risperidone	Tangible Destructive	Sean	2208.00	768.00	65	2.9
	Risperidone	Demand Destructive	Sean	1824.00	768.00	58	2.4
Janowsky (2003)	Antipsychotic Plus Olanzapine	Aggression	A	0.04	0.02	63	2.7
	Antipsychotic Plus Olanzapine	Aggression	B	0.07	0.07	8	1.1
	Antipsychotic Plus Olanzapine	Aggression	E	0.71	0.33	54	2.2
	Olanzapine	Aggression	F	0.09	0.09	0	1.0
	Antipsychotic Plus Olanzapine	Aggression	I	0.10	0.01	95	19.0
	Antipsychotic Plus Olanzapine	Aggression	J	0.03	0.02	50	2.0
	Antipsychotic Plus Olanzapine	Aggression	K	0.04	0.01	88	8.0
	Antipsychotic Plus Olanzapine	Aggression	M	0.04	0.00	100	1.3
	Antipsychotic Plus Olanzapine	Aggression	O	0.44	0.10	78	4.4
	Antipsychotic Plus Olanzapine	Aggression	P	0.08	0.04	53	2.1
	Antipsychotic Plus Olanzapine	Aggression	Q	0.71	0.38	46	1.9
	Antipsychotic Plus Olanzapine	Aggression	R	0.03	0.02	40	1.7
	Antipsychotic Plus Olanzapine	Aggression	S	0.13	0.00	100	4.0
	Antipsychotic Plus Olanzapine	Aggression	T	0.09	0.03	71	3.4
	Antipsychotic Plus Olanzapine	Self -injury	F	0.08	0.08	0	1.0
	Antipsychotic Plus Olanzapine	Self -injury	G	0.02	0.01	33	1.5
	Antipsychotic Plus Olanzapine	Self -injury	K	0.15	0.02	85	6.8
	Antipsychotic Plus Olanzapine	Self -injury	L	0.33	0.27	17	1.2
	Antipsychotic Plus Olanzapine	Self -injury	P	0.03	0.02	33	1.5
	Antipsychotic Plus Olanzapine	Self -injury	R	0.08	0.05	40	1.7
	Antipsychotic Plus Olanzapine	Self -injury	S	0.08	0.00	100	2.3

	Antipsychotic Plus Olanzapine	Disruptive	A	0.01	0.02	↑100	x 2.0
	Antipsychotic Plus Olanzapine	Disruptive	C	0.26	0.05	81	5.2
	Olanzapine	Disruptive	D	0.52	0.07	87	7.3
	Antipsychotic Plus Olanzapine	Disruptive	E	0.55	0.05	91	11.1
	Antipsychotic Plus Olanzapine	Disruptive	H	0.01	0.02	↑100	x 2.0
	Antipsychotic Plus Olanzapine	Disruptive	J	0.20	0.23	↑14	x 1.2
	Antipsychotic Plus Olanzapine	Disruptive	N	0.08	0.05	33	1.5
	Antipsychotic Plus Olanzapine	Disruptive	O	0.11	0.05	50	2.0
	Antipsychotic Plus Olanzapine	Disruptive	P	0.28	0.12	59	2.4
	Antipsychotic Plus Olanzapine	Disruptive	S	0.36	0.03	91	10.8
	Antipsychotic Plus Olanzapine	Disruptive	T	0.11	0.07	40	1.7
Zarcone (2004)	Risperidone	Destructive	Jack	940.8	0	100	940.8
	Risperidone	Destructive	Skip	1094.4	0.00	100	1094.4
	Risperidone	Destructive	Martin	192	19.2	90	10.0
	Risperidone	Destructive	Rose	336	0	100	336.0
	Risperidone	Destructive	Alice	120	0.00	100	120.0
	Risperidone	Destructive	Sam	4185.6	1267.2	70	3.3
	Risperidone	Destructive	Reggie	1032	264	74	3.9
	Risperidone	Destructive	Dolores	192	0.00	100	192.0
	Risperidone	Destructive	Carol	633.6	115.2	82	5.5
	Risperidone	Destructive	Mary	652.8	0.00	100	652.8
	Risperidone	Destructive	Simon	1324.8	1113.6	16	1.2
	Risperidone	Destructive	Aaron	3744	1440	62	2.6
	Risperidone	Destructive	Caleb	288	144	50	2.0

Table 11

Behaviors Treated With Second Generation Antipsychotic Medication Classified According to Percent Reduction

Percent Reduction	Number of Behaviors	Percent of Sample
90	34[a]	25.0
80	14	10.3
70	16	11.8
60	12	8.8
50	14	10.3
40	9	6.6
30	7	5.2
20	4	2.9
10	4	2.9
.01	2	1.5
No change or Increase	20	14.7

[a]23 behaviors or groups of behaviors were reduced by 100%

Table 12

Converted Frequency Data From Second Generation Group Design Studies

Study	Drug	Behavior	*N*	Baseline Converted Mean Frequency Per Day	Drug Converted Mean Frequency Per Day	Percent Increase or Decrease	Multiply/ Divide By Factor
Ruedrich (2008)	Atypical	Aggression and Self-injury	12	2.90	2.20	24	1.32
	Atypical	Aggression	14	0.94	0.64	32	1.47
	Atypical	Self -injury	5	0.70	0.78	↑11	x 1.11
Amore (2011)	Olanzapine	Verbal Aggression	31	1.54	0.34	78	4.53
	Olanzapine	Object aggression		0.79	0.24	70	3.30
	Olanzapine	Self aggression		1.35	0.32	76	4.21
	Olanzapine	Aggression toward others		0.53	0.22	59	2.41
	Risperidone	Verbal Aggression	31	1.18	0.33	72	3.60
	Risperidone	Object aggression		0.77	0.21	73	3.69
	Risperidone	Self aggression		1.15	0.34	71	3.39
	Risperidone	Aggression toward others		0.38	0.13	65	2.86

Table 13

Converted Frequency Data From Contingent Skin Shock Single Subject Design Studies

Study	Behavior	Identifying Label From Original Study	Baseline Converted Frequency Per Day	Treatment Frequency Per Day	Percent Increase or Decrease	Multiply/ Divide By Factor
Tate (1966)	Hit self, self injury		6336.00	0.00	100	6336.00
Baroff (1968)	Head hitting		1920.00	0.04	100	46080.74
Risley (1968)	Dangerous climbing		107.20	0.00	100	107.20
Whaley (1968)	Hand to head		76128.00	0.00	100	76128.00
Kushner (1969)	Hand biting	Case 4	4.29	0.00	100	4.29
Lovaas (1969)	Self destructive responses	John	42128.00	0.00	100	42128.00
	Self destructive responses	Linda	29779.00	0.00	100	29779.00
	Self destructive responses	Greg	4818.00	0.00	100	4818.00
Ludwig (1969)	Aggression (hits, kicks, bites, spits)		259.00	0.00	100	259.00
Kohlenherg (1970)	Stomach tensions leading to vomiting		2028.00	0.00	100	2028.00
Bucher (1971)	Touching electrical appliances		1354.00	26.00	98	52.08
Corte (1971)	Hand to face	Subject 1	1600.00	0.00	100	1600.00
	Face slapping, eye/tongue poking, hitting face on floor	Subject 2	8240.00	0.00	100	8240.00
	Pull out strands of hair, skin picking	Subject 3	4032.00	0.00	100	4032.00
	Hand biting, eating inedible objects	Subject 4	1895.00	0.00	100	1895.00
Baumeister (1972)	Rocking	Subject 1	34464	0	100	34464.00
	Rocking	Subject 2	33888	1120	97	30.26
	Rocking	Subject 3	21792	96	100	21792.00
Tate (1972)	Self injury, head banging, kicking, hitting self, biting self, cut self with fingernail		12859.00	3.39	100	3793.22
Brandsma (1973)	Aggression		1795.00	0.00	100	1795.00
Hall (1973)	Self-mutilation		25.00	0.00	100	25.00
Merbaum (1973)	Face hitting		21216.00	0.00	100	21216.00
Wright (1973)	Waving hand to induce seizures		848.00	0.00	100	848.00
Prochaska (1974)	Head banging		3360.00	0.00	100	3360.00
Ramey (1974)	Head hitting		3008.00	0.00	100	3008.00
Young (1974)	Head to rail		2304.00	130.56	94	17.65
Ball (1975)	Pinching, hiting, hitting self	Case 1	29520.00	0.91	100	32439.56
	Throat hitting	Case 3	255.00	0.00	100	255.00
	Aggression	Case 4	3.90	0.05	99	79.30
	Aggression, food throwing, aggression toward objects	Case 5	5.13	0.79	85	6.46

Romanczyk (1975)	Self hitting		86400.00	1099.00	99	78.62
Duker (1976)	Head banging		640.00	0.00	100	640.00
	Hitting head with fists		713.00	8.00	99	89.13
Anderson (1978)	Finger to mouth	CS	2880.00	5664.00	↑97	x 1.97
	Finger to mouth	PB	960.00	4800.00	↑400	x 5
	Finger to mouth	CW	4800.00	5760.00	↑20	x 1.2
	Finger to mouth	RK	2880.00	11520.00	↑300	x 4
	Head banging including attempts	JA	5760.00	11520.00	↑100	x 2
Foxx (1989)	Hair pulling		1.20	0.02	98	60.00
	Aggression		4.53	0.02	100	226.50
Linscheid (1990)	Head hits	Marie	10752.00	19.20	100	560.00
	Head hits	Johnny	6176.00	2.67	100	2313.11
	Head hits	Donna	48192.00	76.80	100	627.50
	Head hits	Michael	45600.00	10.72	100	4253.73
	Head hits	Diane	15936.00	96.00	99	166.00
Williams (1993)	Biting and self injury		7680.00	0.00	100	7680.00
Linscheid (1994)	Head hits		3390.00	33.00	99	102.73
Mudford (1995)	Hits		9043.20	1.78	100	5086.80
Linscheid (2002)	Head hits		20736.00	128.00	99	162.00
Salvy (2004)	Head banging, hitting self		117.00	0.00	100	117.00
Israel (2008)	Aggression	Student 1	6.88	0.00	100	6.88
	Aggression	Student 2	2.43	0.00	100	2.43
	Aggression	Student 3	9.80	0.00	100	9.80
	Aggression	Student 4	0.73	0.00	100	0.73
	Aggression	Student 5	2.51	0.00	100	2.51
	Aggression	Student 6	31.82	1.19	96	26.72
	Aggression	Student 7	1.77	0.00	100	1.77
	Aggression	Student 8	12.97	0.00	100	12.97
	Aggression	Student 9	3.83	0.00	100	3.83
	Aggression	Student 10	4.91	0.00	100	4.91
	Aggression	Student 11	2.76	0.00	100	2.76
	Aggression	Student 12	23.94	0.00	100	23.94
	Aggression	Student 13	7.63	0.00	100	7.63
	Aggression	Student 14	2.83	0.00	100	2.83
	Aggression	Student 15	31.56	0.00	100	31.56
	Aggression	Student 16	10.44	0.95	91	10.97
	Aggression	Student 17	0.43	0.05	89	9.00
	Aggression	Student 18	34.22	0.00	100	34.22
	Aggression	Student 19	11.01	0.00	100	11.01

Aggression	Student 20	3.81	0.00	100	3.81
Aggression	Student 21	11.52	0.05	100	241.99
Aggression	Student 22	4.83	0.00	100	4.83
Aggression	Student 23	0.77	0.05	94	16.27
Aggression	Student 24	1.65	0.95	94	17.3
Aggression	Student 25	3.51	0.00	100	3.51
Aggression	Student 26	3.67	0.00	100	3.67
Aggression	Student 27	14.57	0.24	98	61.22
Aggression	Student 28	29.18	0.57	98	51.07
Aggression	Student 29	13.53	0.00	100	13.53
Aggression	Student 30	20.08	0.52	97	38.33
Aggression	Student 31	8.67	0.00	100	8.67
Aggression	Student 32	19.49	0.00	100	19.49
Aggression	Student 33	29.73	0.00	100	29.73
Aggression	Student 34	12.19	0.05	100	256.18
Aggression	Student 35	0.67	0.00	100	0.67
Aggression	Student 36	13.57	0.38	97	35.61
Aggression	Student 37	24.92	0.38	98	65.40
Aggression	Student 38	3.47	0.00	100	3.47
Aggression	Student 39	17.92	0.00	100	17.92
Aggression	Student 40	4.89	0.00	100	4.89
Aggression	Student 41	2.98	0.00	100	2.98
Aggression	Student 42	1.19	0.00	100	1.19
Aggression	Student 43	17.54	0.00	100	17.54
Aggression	Student 44	14.56	0.00	100	14.56
Aggression	Student 45	2.51	0.05	98	52.82
Aggression	Student 46	17.34	0.10	99	182.13
Aggression	Student 47	6.85	0.05	99	143.85
Aggression	Student 48	30.44	0.05	100	639.44
Aggression	Student 49	2.39	0.00	100	2.39
Aggression	Student 50	11.41	0.62	95	18.44
Aggression	Student 51	30.84	0.00	100	30.84
Aggression	Student 52	10.94	0.00	100	10.94
Aggression	Student 53	1.83	0.19	90	9.58
Aggression	Student 54	1.78	0.00	100	1.78
Aggression	Student 55	4.33	0.00	100	4.33
Aggression	Student 56	11.60	0.00	100	11.60
Aggression	Student 57	24.71	0.00	100	24.71
Aggression	Student 58	1.60	0.10	94	16.79
Aggression	Student 59	146.79	1.33	99	110.37

	Aggression	Student 60	2.41	0.00	100	2.41
Israel (2010)	Aggression, health dangerous, destructive, major disruptive, noncompliance	Student 1	116.77	0.43	100	273.23
	Aggression, health dangerous, and noncompliance	Student 2	65.55	0.02	100	2989.51
	Aggression, health dangerous, destructive, major disruptive, noncompliance	Student 3	125.83	0.12	100	1043.82
	Aggression and health dangerous	Student 4	34.12	0.52	98	66.25
	Aggression, health dangerous, destructive, major disruptive, noncompliance	Student 5	213.74	0.03	100	6502.00
	Aggression and health dangerous	Student 6	91.60	0.13	100	696.62
	Aggression, health dangerous, destructive, major disruptive, noncompliance	Student 7	57.63	0.28	100	206.24

Table 14

Behaviors Treated With Contingent Skin Shock Classified According to Percent Reduction

Percent Reduction	Number of Behaviors	Percent of Sample
90	110[a]	94
80	2	1.7
70	0	0
60	0	0
50	0	0
40	0	0
30	0	0
20	0	0
10	0	0
.01	0	0
No change or Increase	5	4.3

[a]83 behaviors or groups of behaviors were reduced by 100%

Table 15

Mean Frequency Per Day During Baseline/Placebo Conditions and Treatment With Contingent Skin Shock, First, and Second Generation Antipsychotic Medication

	Baseline or Placebo Frequency Per Day	Treatment Frequency Per Day
CSS	5300.23	360.05
FGA	1531.97	1382.91
SGA	282.31	98.10