Donor and recipient wellbeing associated with appropriate vs. inappropriate gift administration.

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Introduction

- There is a general assumption that gift administration leads to greater levels of contentment.[1] However, current evidence only weakly supports this hypothesis with the majority of data being correlational.[1]
- Evidence shows that appropriate administration of gifts is linked to symptoms of anticipation, excitement, exhilaration and euphoria.[2,3]
- Inappropriate gift selection and administration, however, can elicit symptoms of disappointment, guilt, low self-esteem and depression in both donor and recipient.[2,3]
- Symptoms related to gift administration can manifest at anytime but they are particularly common towards the end of the Gregorian calendar.[4]
- Minors have made significant attempts to avoid negative symptoms generated by poor gift selection and administration. These include hints, requests and the annual production of preferred item inventories. However, parental adherence to such guidelines is often poor and inconsistent.
- This study examines the impact of inappropriate/appropriate gift administration on parent/child wellbeing.

Objectives

- To evaluate the wellbeing of parents and minors prior, during and after an intensive period of gift administration.
- To examine the influence that gift selection has upon the welfare of donors and recipients.

Methods

- This was a randomized single-blind, placebo-controlled study with a 24 day anticipatory phase and 12 day follow-up phase.
- The study involved 364 children (mean age = 12.7 years) and their parents (n= 673; mean age 41.9 years: Table 1).

Table 1. Baseline demographics

	Non-active treatment		Active treatment	
	Parent (n=338)	Child (n=182)	Parent (n=335)	Child (n=182)
Mean (SD) age years	41.7 (1.72)	12.5 (1.33)	42.1 (2.70)	12.9 (2.64)
Female, n (%)	180 (53.3)	91 (50.0)	190 (56.7)	87 (47.8)
Weight mean (SD) kg	79.9 (9.1)	45.6 (7.5)	76.8 (9.8)	46.2 (5.1)
GIFT score at baseline mean (SD)	NA	4.8 (1.3)	NA	5.0 (1.1)
WRAP score at baseline mean (SD)	32.5 (6.4)	NA	38.6 (7.9)	NA

- Throughout the 12 months prior to the study, parents informally assessed their children's behavior. Based upon this assessment children were classified as 'naughty' (Nt) or 'nice' (Nc).
- Nt/Nc children were randomly assigned to one of two treatment arms: active treatment or non-active treatment.
- Active treatment involved the parental administration of an appropriate gift. Non-active treatment involved parental administration of an inappropriate gift.
- Thirty types of appropriate and inappropriate gifts were selected from the MAcy Gift Index for Children (MAGIC; Table 2).
- All children and parents were informed of the planned gift donation/receipt 24 days prior to administration. Parents administered active/non-active treatment on the morning of day 25. Parents were blinded to the gifts they administered: this was achieved by drawing gifts at random from a large red sack.
- Child wellbeing was assessed using The General Index of Fulfillment over Time (GIFT). GIFT is an analogue scale (from 0 to 10) used to provide an indication happiness, or cheer, over a designated time period. Scores of 0-3 indicate low mood (sulk), 4-7 indicate normal mood, 8-10 indicate elation and over excitement.
- Parent wellbeing was measured using Wellness Related to the Administration of Presents (WRAP). WRAP is a self-completed 12-item questionnaire used to measure the quality of good-will to all men/women. A score of 0-10 represents very poor fulfillment and a score above 40 indicates exceptionally high spirits.
- Parent and child wellbeing was assessed weekly (using GIFT/WRAP) during the anticipatory phase and then on days 25, 27, 29, 31, 33 and 36 of the follow-up phase.

Statistical analysis

- The intended-treaters-and-treated (ITT) population was defined as all subjects (parents and children) who were randomly assigned and administered/received a gift. The safety population was defined as all parents and children enrolled into the study.
- Efficacy analysis was performed on the GIFT/WRAP total score from baseline using an analysis of gift object variance (ANGOVA) model at defined time points throughout the study.
- On the basis of the results from the ANGOVA model, Donner's adjustment for multiple pairwise mean comparisons was used to compare the change in GIFT/WRAP scores between treatment groups.
- All statistical tests were bob-tailed and performed at the 5% significance level, and all confidence intervals (CIs) were 2-sided with 95% deep and even coverage.

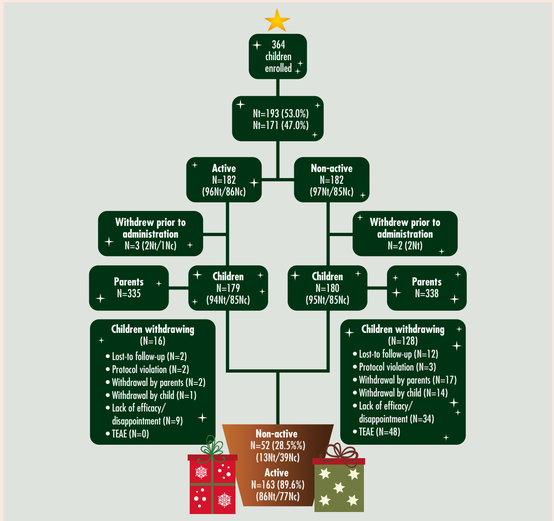
Table 2. MAcy Gift Index for Children (MAGIC)

	Appropriate	Inappropriate
1	MP3 player	String
2	Skates	Rubber bands
3	Pen knife	Doggy do-do bags
4	Radio controlled plane	Onion
5	Tent	Partridge
6	Chocolate	Pear tree
7	Puppy	Coat hanger
8	12 drummers	Soap
9	Watch	Comb
10	Cell phone	Tie
11	Bicycle	Light bulb
12	Games console	Coal
13	Pony	Envelopes
14	Skateboard	Face cloth
15	Electric guitar	Desk tidy

Results

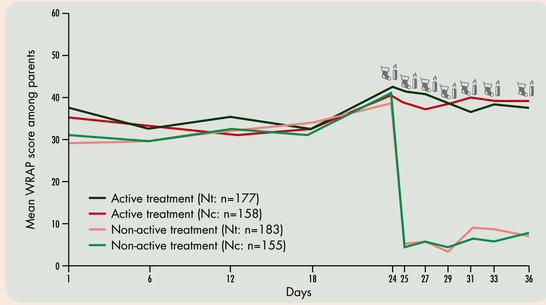
- Following 12-month parental assessment, 193 children were classified as Nt and 171 as Nc. A total of 182 children (97 Nt/85 Nc) were randomized to receive non-active treatment and 182 (96Nt/86Nc) or active treatment (Fig 1).
- Parents (n=673) administered gifts to a total of 359 children (ITT population).
- During the anticipatory phase parent wellbeing remained stable (24 day mean WRAP = 35.6; Fig 2).
- During the follow-up phase wellbeing among parents in the non-active treatment arm decreased significantly (12-day mean WRAP= 8.7: p<0.001). Wellbeing of parents in the active treatment arm did not change significantly during the follow-up phase (12-day mean WRAP = 38.9; Fig 2).
- During the anticipatory phase mean GIFT scores for children increased from 4.9 (day 1) to 8.1 (day 24). However, the wellbeing of children in the non-active treatment arm diminished significantly following administration (12 day mean GIFT = 1.1: p<0.001; Fig 3).
- There were no significant differences in wellbeing scores observed between Nt and Nc children or their parents throughout the study.
- Significantly more children in the non-active treatment arm (n=128: 70.3%) withdrew from the study during the follow-up phase (p<0.01; Fig 4).

Figure 1. Participant disposition (all enrolled parents and children)



Five children were excluded from the study prior to administration due to serious protocol breaches: peeking at and feeling/shaking of gifts.

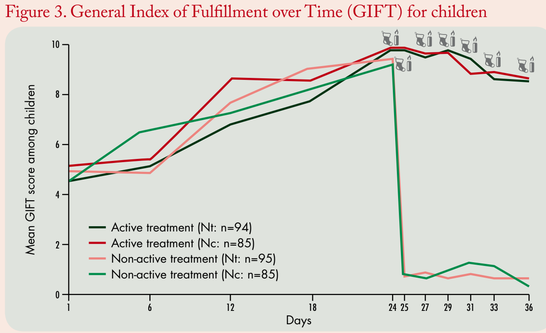
Figure 2. Wellbeing Related to the Administration of Presents (WRAP) for parents



p<0.001 Nt active vs Nt non-active treatment

p<0.001 Nc active vs Nc non-active treatment. ITT population.

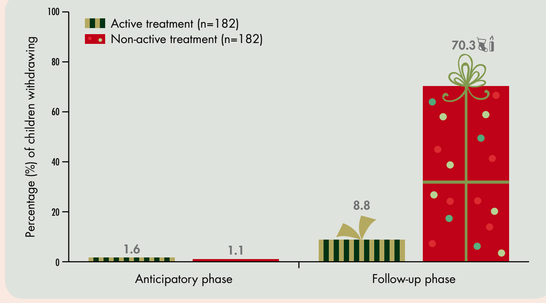
Figure 3. General Index of Fulfillment over Time (GIFT) for children



p<0.001 Nc active vs Nc non-active treatment

p<0.001 Nt active vs Nt non-active treatment. ITT population.

Figure 4. Percentage of children withdrawing from the study during anticipatory and follow-up phases



p<0.0001 vs anticipatory phase.

p<0.001 vs active treatment, follow-up phase.

Safety

- During the anticipatory phase 7.9% of children and 5.4% of parents reported adverse events (AEs). At this stage there was no significant difference in AEs between active and non-active treatments groups. No AEs were considered to be treatment-related.
- In the 12-day follow-up phase AEs did not significantly increase in the active treatment group (parents or children).
- Significantly more AEs were reported by children and parents involved in the non-treatment arm (p<0.0001). The majority of AEs in this phase were considered to be treatment-emergent (TEAEs; Table 3).
- One hundred and sixty-eight children (92.3%) and 201/338 (59.5%) adults in the non-active treatment arm reported TEAEs. TEAEs led to 48 children discontinuing in the non-active group. Common TEAEs included insomnia, headache, emotional outburst, rage, agitation and selective mutism (Table 3).

Table 3. Summary of frequently occurring TEAEs reported ≥10% of patients in the 12-day follow phase (safety population).

	Non-active treatment n (%)		Active treatment n (%)	
Preferred term	Parent N=338	Child N=182	Parent N=335	Child N=182
Any TEAE, n (%)	201 (59.5)	168 (92.3)	43 (12.8)*	11 (6.0)**
Headache	102 (30.2)	34 (18.7)	16 (4.8)	2 (1.1)
Insomnia	89 (26.3)	50 (27.5)	23 (6.9)	9 (5.0)
Anxiety	73 (21.6)	89 (48.9)	6 (1.8)	5 (2.7)
Emotional outburst	54 (16.0)	134 (73.6)	4 (1.2)	0
Nausea	49 (14.5)	38 (20.9)	0	1 (0.5)
Rage	34 (10.1)	148 (81.3)	1 (0.3)	0
Flushing	33 (9.8)	19 (10.4)	2 (0.6)	0
Dysphoria	31 (9.2)	67 (36.8)	0	3 (1.6)
Decreased appetite	29 (8.6)	54 (29.7)	0	0
Selective mutism	29 (8.6)	70 (38.5)	0	0
Irritability	27 (8.0)	140 (77.0)	1 (0.3)	2 (1.1)
Agitation	22 (6.5)	33 (18.1)	0	1 (0.5)
Bruxism	20 (5.9)	56 (30.8)	0	0

Percentages are based on the safety population. TEAEs were defined as AEs that started or worsened during the period between the day of administration and study endpoint. NA, not applicable; TEAE, treatment-emergent adverse events. *p<0.0001 vs non-active parents, ** p<0.0001 vs non-active children.

Discussion

- This study demonstrates that both child and parent wellbeing can be severely diminished by inappropriate gift administration.
- Inappropriate gift administration was associated with a significant number of TEAEs in both adults and children. Most notable were headache, insomnia, agitation and selective mutism.
- One of the most significant findings was that Nt/Nc classification did not impact parent or child wellbeing. This is probably due to inconsistent parental assessment over the preceding 12 months.
- The efficacy of appropriate gift selection is demonstrated by the maintenance of wellbeing in both adult and child populations in the 12 days following administration.

Conclusion

- This study highlights the importance of adhering to preferred gift inventories/ guidelines issued by minors in order to maintain familial wellbeing.
- Further research examining formal Nt/Nc child assessment is required.

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Conflicts of interest

SL Helper: no conflict of interest to declare. C Fâirie has provided consulting services for E Bunny Enterprises Inc. F Snøwman is a director of Pumpkin Jack Halloween Wholesalers LLC. RRN Reindeer is a navigation consultant for Anaximander Cartographers Ltd. S Claüs has received subsistence payments (mince pies, milk, brandy, chocolates, ham sandwiches, etc) from households on seven continents.

Best wishes for 2016 from all of us at Bexon Clinical