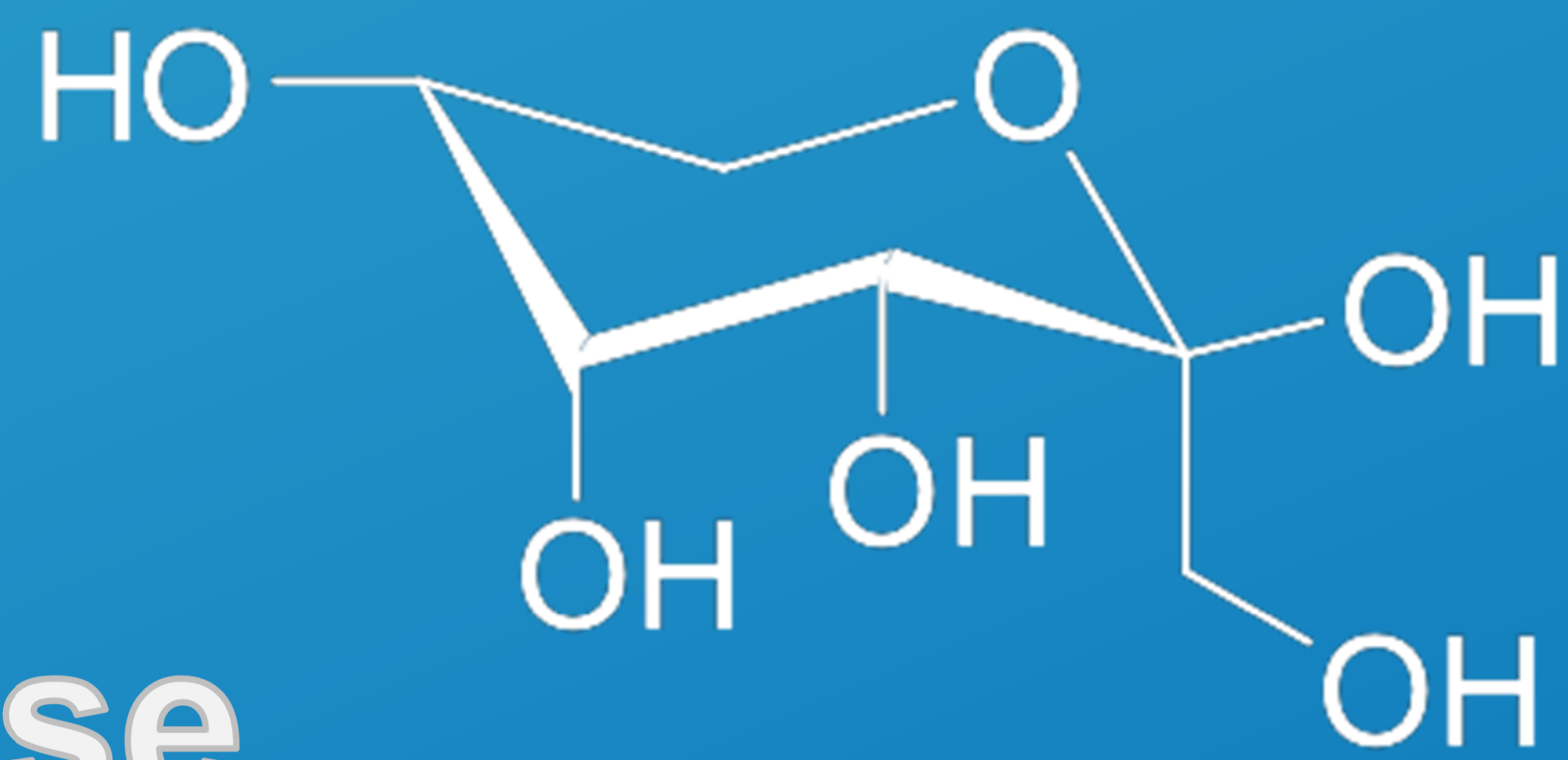


56 g allulose



per day as sweetener is generally well tolerable without relevant gastrointestinal symptoms in healthy adults

GASTROINTESTINAL TOLERABILITY OF D-ALLULOSE IN ADULTS – RESULTS OF A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

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Background:

- sugar consumption → adverse health outcomes, e.g., obesity, type-2 diabetes, and cardiovascular disease.
- D-allulose: ~70% of sucrose's sweetness, Generally Recognized as Safe (GRAS) by FDA
- current evidence on its gastrointestinal (GI) tolerability is limited

Methods:

- randomized, double-blind, placebo-controlled trial
- intervention:
 - three dosages of D-allulose (0.3, 0.4, and 0.5 g/kg body weight [BW] twice daily) compared to
 - placebo (D-glucose 0.5 g/kg BW twice daily)
 - over seven days in 48 healthy adults
- GI tolerability endpoints:
 - Gastrointestinal Symptom Rating Scale (GSRS),
 - stool frequency and consistency using the Bristol Stool Form Scale (BSFS),
 - subjective global tolerability, and
 - adverse events (AEs)

Results:

- dose-dependent increases in GI symptoms over placebo (Fig. 1A) in the GSRS domains indigestion, diarrhoea, and abdominal pain (Fig. 1B)
- no statistically significant differences in total GSRS between placebo and D-allulose at lower dosages (2x0.3 and 2x0.4 g/kg BW/day),
- statistically significant differences in GSRS between placebo and highest dosage (2x0.5 g/kg BW/day) scores
- D-allulose dose-dependently increased stool frequency (Fig. 2)
- mean BSFS scores for the two lower D-allulose dosages were between 3 and 5 (normal range), whereas for the highest D-allulose dosage, mean BSFS scores were above the normal range, indicating softer stools/diarrhea
- global tolerability ratings aligned with the GI tolerability outcomes, with mainly excellent or good ratings for the two lower dosages (Fig. 3)
- seven non-serious AEs were observed across groups, none considered as related to the study interventions

Conclusion: Up to 0.4 g/kg BW twice daily D-allulose are well tolerated.

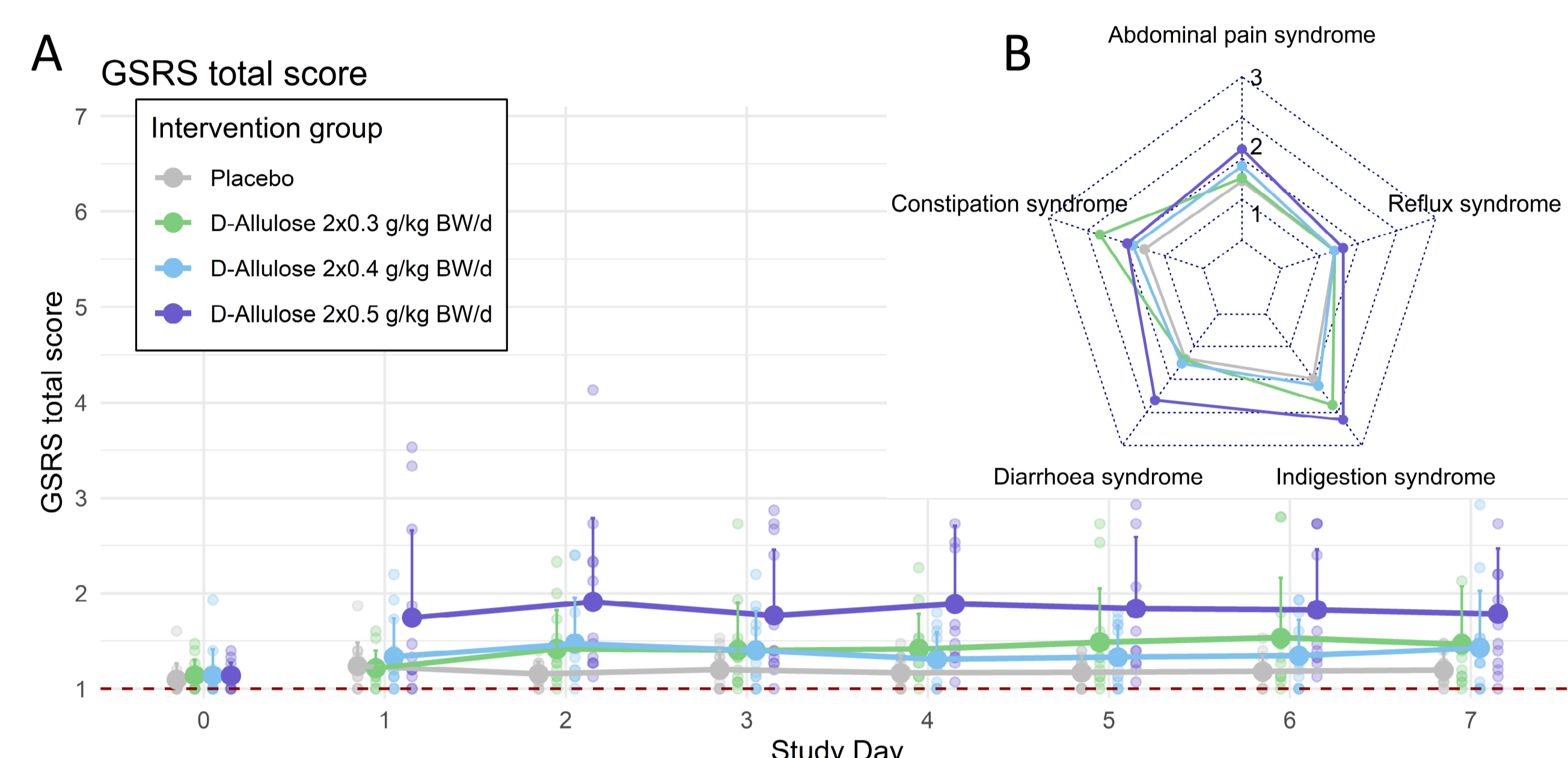


Fig. 1: A) Total GSRS over time per intervention group; large opaque circle: mean value per group and day; small semitransparent circles: individual scores; error bar: standard deviation; B) Spider plot of the five GSRS domain scores per intervention group on day 7

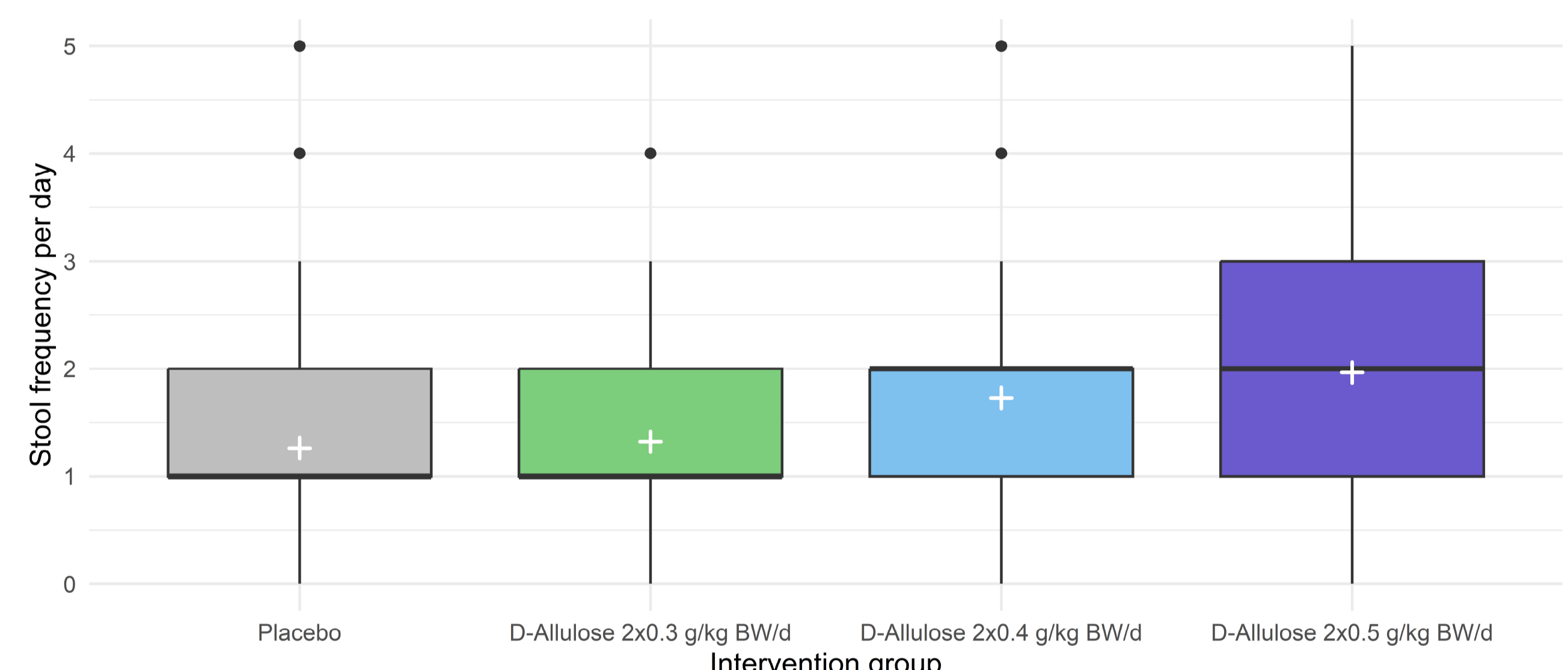


Fig. 2: Stool frequency per day for each intervention group; box: 25-75% interquartile range, thick line: median, white cross: mean, whiskers: range to last individual data point; points: extreme outliers

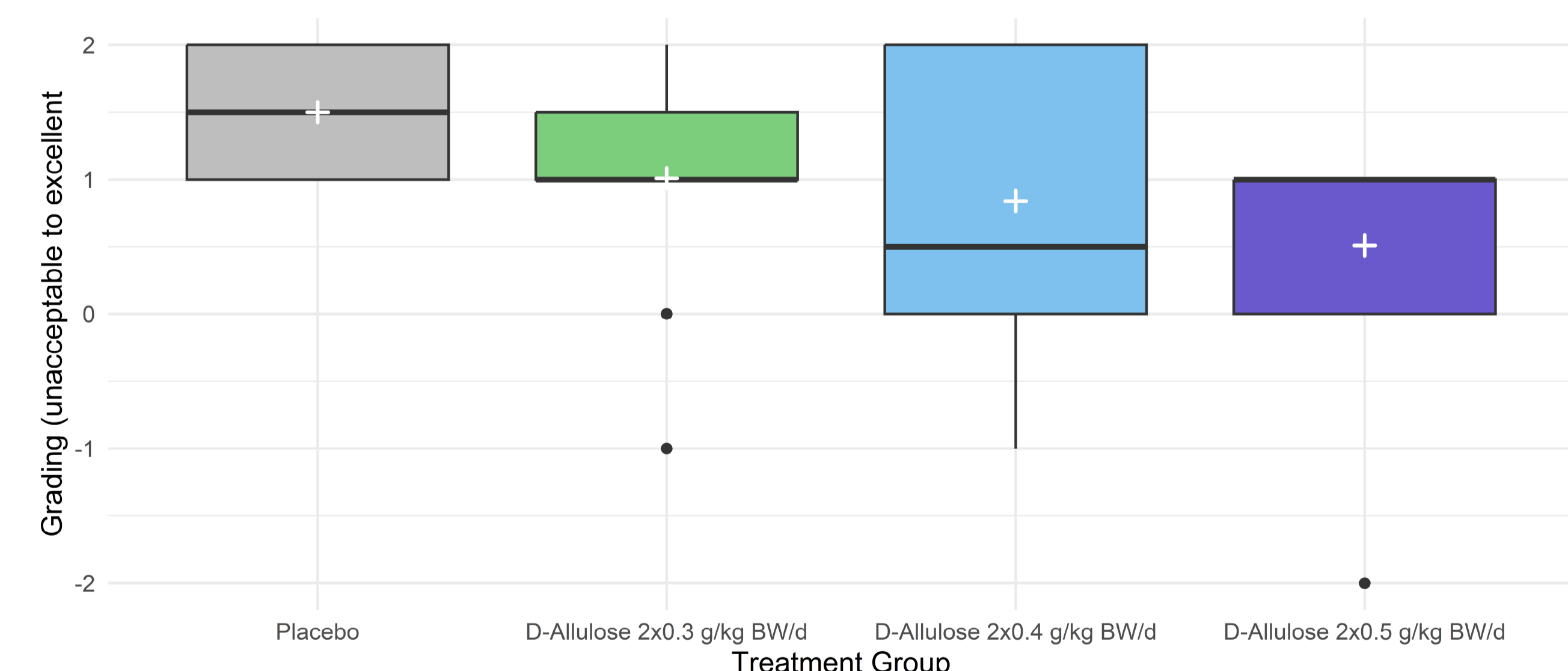


Fig. 3: Global tolerability ratings on a 5-point Likert scale; -2: unacceptable, -1: poor, 0: fair, 1: good, 2: excellent



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